87 1063

Supreme Court, U.S.
FILED
DEC 23 1987
JOSEPH F. SPANIOL, JR.
CLERK

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1987

NO. _____

RONALD G. WOLIN,
Individually and on Behalf
of All Others Similarly Situated,
Petitioner

v.

THE UNITED STATES OF AMERICA,
U.S. FOOD & DRUG ADMINISTRATION,
KENNETH P. EWING, SHARYN MILLER, and
Other Unknown Agents of the Food & Drug
Administration and the United States of America,
Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STUART M. NELKIN
NELKIN & NELKIN, P.C.
5417 Chaucer
P.O. Box 25303
Houston, Texas 77265

MARGARET A. HARRIS
NELKIN & NELKIN, P.C.
5417 Chaucer
P.O. Box 25303
Houston, Texas 77265

Counsel for Petitioner

QUESTIONS PRESENTED

1. Whether medical patients have standing to challenge the seizure of their medical records by federal agents from the premises of their treating physician?

2. Whether the search warrant upon which the seizure of all patient records from a medical clinic was predicated was a general and overly-broad warrant in violation of the fourth amendment?

3. Whether the search warrant used to seize all patient records from a medical clinic was not supported by probable cause, contrary to the fourth amendment?

4. Whether federal agents violated the norms of clearly established law when they obtained and executed a search warrant to seize all patients' medical records from the offices of the patients' treating physician?

SUBJECT INDEX

	Page
QUESTIONS PRESENTED	I
OPINIONS BELOW	2
JURISDICTION	2
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	2
STATEMENT OF THE CASE	3
REASONS FOR GRANTING THE WRIT	8
CONCLUSION	24
CERTIFICATE OF SERVICE	25

LIST OF AUTHORITIES
CASES

	Page
Anderson v. Creighton, __ U.S. __, 107 S.Ct. 3034 (1987)	23
Andresen v. Maryland, 427 U.S. 463 (1976)	16
California v. Ciraolo, __ U.S. __, 106 S.Ct. 1809 (1986)	9, 10
Ex Parte Jackson, 96 U.S. 727 (1878)	11
Illinois v. Gates, 462 U.S. 213 (1983)	19, 22
In re Lafayette Academy, 610 F.2d 1 (1st Cir. 1979)	14
Malley v. Briggs, 475 U.S. 335 (1986)	24
Nathanson v. United States, 290 U.S. 41 (1933)	15, 20, 21
O'Connor v. Ortega, __ U.S. __, 107 S.Ct. 1492 (1987)	12

Pyramid Life Insurance Co. v. Masonic Hospital Ass'n of Payne County, 191 F. Supp. 51 (W.D. Ok. 1961) 9
Rakas v. Illinois, 439 U.S. 128 (1978) 9
Sgro v. United States, 287 U.S. 206 (1932) 21
Shaffer v. Wilson, 523 F.2d 174 (10th Cir. 1975), *cert. denied*, 427 U.S. 912 (1976) 18
Sovereign News Company v. United States, 690 F.2d 569 (1st Cir. 1982), *cert. denied*, 464 U.S. 814 (1983) 18
United States v. Abrams, 615 F.2d 541 (1st Cir. 1980) 16, 17
United States v. Chapman, 559 F.2d 402 (5th Cir. 1977) 18
United States v. Westinghouse, 638 F.2d 570 (3d Cir. 1980) 11
VonderAhe v. Howland, 508 F.2d 364 (9th Cir. 1974) 12, 13
Whalen v. Roe, 429 U.S. 589 (1977) 11

UNITED STATES CONSTITUTION

Fourth Amendment ..... *passim*

UNITED STATES STATUTES

	Page
5 U.S.C. § 552(b)(6)	11
18 U.S.C. § 286	15
18 U.S.C. § 287	15
18 U.S.C. § 371	15
18 U.S.C. § 401	15
18 U.S.C. § 1001	15
18 U.S.C. § 1341	15
18 U.S.C. § 1505	15
21 U.S.C. § 331(d)	15
21 U.S.C. § 374	6
28 U.S.C. § 1254(1)	2
28 U.S.C. § 1331	6
28 U.S.C. § 1361	6
42 U.S.C. § 1983	3

APPENDICES

Page

APPENDIX A - Judgment of the United States Court of Appeals for the Fifth Circuit, June 25, 1987..... 1a

APPENDIX B - Order of United States District Court for the Southern District of Texas, January 21, 1986..... 30a

APPENDIX C - Order of United States District Court for the Southern District of Texas, January 21, 1986..... 41a

APPENDIX D - Search Warrant on Written Affidavit for an Office Complex at 6221 Corporate Drive, Houston, Texas 43a

APPENDIX E - Order of the United States Court of Appeals for the Fifth Circuit, August 26, 1987..... 65a

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1987

NO. _____

RONALD G. WOLIN,
Individually and on Behalf
of All Others Similarly Situated,
Petitioner

v.

THE UNITED STATES OF AMERICA,
U.S. FOOD & DRUG ADMINISTRATION,
KENNETH P. EWING, SHARYN MILLER, and
Other Unknown Agents of the Food & Drug
Administration and the United States of America,[1]
Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

The Petitioner, Ronald G. Wolin, individually and on behalf of all others similarly situated, respectfully prays that a writ of certiorari issue to review the judgment and opinion

---

[1] In the court below, the parties also included Stanislaw R. Burzynski, M.D., and the Burzynski Cancer Research Institute, who were defendants in the civil action originally filed by the United States on March 30, 1983. In 1985, Petitioner, Juanice Kuharzyk, Richard A. Sharp, William L. Cody, Lilian Shore, and Ellen E. Trocchio, individually and on behalf of all others similarly situated, intervened with a counterclaim against Respondents.

of the United States Court of Appeals for the Fifth Circuit entered in this proceeding on June 25, 1987.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 798 F.2d 731 (1987) and is reprinted here as Appendix A.

The United States District Court for the Southern District of Texas entered two memorandum orders on January 21, 1986, which were not reported but have been reprinted here as Appendices B and C.

JURISDICTION

The judgment of the United States Court of Appeals for the Fifth Circuit was entered on June 25, 1987. Petitioner filed a Petition for Rehearing on July 17, 1987, which was denied on August 26, 1987. On November 17, 1987, Justice White signed an order extending the time for filing this Petition for Certiorari to and including December 23, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Fourth Amendment, United States Constitution:

"The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated and no Warrants shall issue, but upon probable cause, supported by Oath or

affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

United States Code, Title 42:

§ 1983. Civil action for deprivation of rights.

"Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia."

STATEMENT OF THE CASE

In September 1983, Petitioner Ronald G. Wolin was diagnosed as having a form of cancer known as lymphocytic lymphoma. (R.325). The next year, he became a patient of Stanislaw R. Burzynski, M.D. in Houston, Texas. (R.325). Following the general practice of medical patients, Wolin entrusted his medical records, with test results, medical history, progress notes, and narratives to Dr. Burzynski when he began receiving treatment for his cancer. The information contained within these medical records is, of course, highly personal and private. (TR. Vol. X, at IV-79-82; Vol. VI, at II-A-19).

On July 17, 1985, Mr. Wolin's medical records, and those of all other current and former patients of Dr. Burzynski, were callously seized from Dr. Burzynski's clinic by federal agents armed with a general warrant that was unsupported by probable cause. Over two years have passed since the seizure of the medical records, during which time no criminal charges have been lodged against Dr. Burzynski or any of his associates. Nonetheless, despite the requests, pleas, and prayers of the doctor's patients, including Petitioner, the government has not returned these vital medical records.[2]

Petitioner's medical records were seized after a string of incidents in which agents of the federal government sought unsuccessfully in federal district court to prevent Dr. Burzynski from treating patients in the State of Texas. This proceeding officially began two years before the seizure of the medical records when the United States filed a civil action against Stanislaw R. Burzynski, M.D. and others, alleging certain violations of the Food, Drug and Cosmetic Act, and requesting injunctive relief prohibiting the defendants from manufacturing and distributing

---

2 The Petitioner's and other patients' concern that their medical records be returned is not merely an intellectual exercise. Should a patient be in need of emergency medical attention, the wrong treatment could be given if the patient's medical records are not immediately available to the treating physician. As a result, the patient could die. (TR. Vol. X, at IV-61-89). The threat posed to Petitioner and other patients because of the government's continued retention of their medical records is thus extraordinarily severe.

antineoplastons, a new drug for cancer treatment.[3] (R.1339). Shortly thereafter, the district court granted the government's request for permanent injunctive relief as to interstate shipments of Dr. Burzynski's new drug, but upheld Burzynski's right to administer the drug to patients within the State of Texas. (R.649-53).

On July 17, 1985, four agents of the U.S. Food and Drug Administration ("FDA") descended upon Dr. Burzynski's medical clinic with a search warrant and seized virtually all documents in that facility. It took the officers approximately 6-8 hours to seize and remove the records. (TR Vol. XIII, at VII-4). (A copy of the search warrant, the supporting affidavit, and the officer's return is attached as App. D at pp. 43a through 64a).

The Court of Appeals found that the application for and execution of the criminal search warrant was undertaken by Respondents "to determine whether Dr. Burzynski had violated the Act and other federal criminal statutes by failing to adhere to the requirements of the permanent injunction entered by the district court in May 1983." App. A at p. 12a. Respondents, however, had available to them other less drastic alternatives to determine whether Dr. Burzynski had failed to comply with the injunction previously entered in the 1983 civil action. The district court had, for example, specifically retained jurisdiction to enforce its injunction. (R.653). Respondents therefore could have sought access to

---

3 Antineoplastons are fractions isolated from amino acids that are either produced by living organisms or created synthetically. (TR Vol. V, at I-6-11).

whatever records were necessary to their investigation in an orderly, non-disruptive and non-life threatening manner simply by invoking ordinary civil discovery procedures.[4]

Following the wholesale seizure of their medical records, Petitioner Ronald G. Wolin and other patients of Dr. Burzynski intervened individually and on behalf of all others similarly situated in the on-going civil proceeding and filed a counterclaim against the United States of America, the FDA, and various government agents of the FDA.[5] (R.321-39). The patients sought both damages and injunctive relief, arguing primarily that the seizure of their medical records violated their constitutional rights. (R.321-39). The patients invoked the district court's continuing jurisdiction, 28 U.S.C. §§ 1331 and 1361, and the first, third, fourth, fifth, and ninth amendments to the United States Constitution. (R.324). The patients also filed a Motion for Return of Property pursuant to Rule 41 of the Federal Rules of

---

4 Under its statutory authority, the FDA had lawful access to Dr. Burzynski's clinic. 21 U.S.C. § 374. (TR Vol. XIII, at VII-17-18). Pursuant to that statutory authorization, in fact, the government conducted several inspections of Dr. Burzynski's medical clinic. (TR Vol. III, at B-153; Vol. XIII, at VII-20-30). During these inspections, Dr. Burzynski allowed the government access to all documents it sought to review. The only documents ever alleged by the government to have been withheld were patient billing records and insurance records. App. D at p. 63a. These records, however, could have readily been obtained by a Request for Production of Documents pursuant to Rule 34 of the Federal Rules of Civil Procedure.

5 Dr. Burzynski also filed a counterclaim against the Respondents and has actively litigated his claims throughout this proceeding. This Petition, however, addresses only the issues raised by Petitioner and the other patients of Dr. Burzynski.

Criminal Procedure (R.277), which was denied on October 9, 1985. (R.320; TR Vol. IV, at 1A-84).

On January 21, 1986, the district court entered a written order denying the patients' Motion for Preliminary Injunction and Motion for Return of Property. (R.12-20). App. B at pp. 30a through 40a. Although the patients' preliminary injunction motion had not, to that point, even been heard by the district court (TR Vol. XII, at VI-152), the district court based its denial of this motion on its conclusion that the patients had "failed in their burden to establish that they have a superceding right to return of the patient records ... [and thus] are unable to demonstrate a likelihood of success on their Motion for Preliminary Injunction." (R.19). App. B at p. 39a.

Also on January 21, 1986, without citing any additional reasons, the district court entered its written order dismissing the patients' Counterclaim for failure to state a claim upon which relief could be granted. (R.24-25). App. C at pp. 41a through 42a.

On appeal, a panel of the United States Court of Appeals for the Fifth Circuit affirmed the district court's dismissal of the patients' damage claims against the government and its agents in their individual capacities. App. A at pp. 1a through 29a. The Court of Appeals additionally concluded that the patients did not have standing to seek return of the seized records because they did not have a "legitimate expectation of privacy in the records maintained by Dr. Burzynski that could be asserted against the search warrant." App. A at p. 20a. The Court of Appeals then ruled that, even

assuming the patients had standing to seek return of their medical records, "they alleged no basis on which the district court could have found the seizure of the records unlawful." App. A at p. 20a.

REASONS FOR GRANTING THE WRIT

1. IN A DECISION WITH FAR-REACHING IMPACT, THE COURT OF APPEALS HAS RULED, CONTRARY TO PRIOR DECISIONS OF THIS COURT, THAT, REGARDLESS OF MEDICAL PATIENTS' EXPECTATIONS OF PRIVACY, THEY HAVE NO STANDING TO CHALLENGE THE SEIZURE OF THEIR RECORDS PROPERLY MAINTAINED IN A DOCTOR'S OFFICE.

In support of its holding that patients lack standing to challenge the seizure of their medical records from their doctor's clinic, and thus lack standing to urge the return of their medical records, the Court of Appeals offered two reasons, both of which conflict with prior decisions of this Court. First, the Court of Appeals held that the patients' property interest in their medical treatment records was insufficient to demonstrate their entitlement to lawful possession of the records. Second, the Court of Appeals concluded that patients have no legitimate expectation of privacy surrounding the contents of medical records found in their doctor's clinic because no physician-patient privilege exists in the context of federal criminal proceedings.

The first reason relied upon by the Court of Appeals was based upon the erroneous belief that property law concepts

precluded the patients from asserting their fourth amendment rights. Under applicable constitutional standards, whether patients have a property interest in their records is irrelevant.[6] In *Rakas v. Illinois*, this Court emphatically rejected the notion that "arcane distinctions developed in property and tort law" determine whether society is willing to recognize an expectation of privacy as legitimate. 439 U.S. 128, 143 (1978). Thus, contrary to the holding of the Court of Appeals, property and tort concepts do not, under this Court's precedents, control Petitioner's right to assert the protection of the fourth amendment. Instead, the focus of the Court of Appeals in analyzing the important and far-reaching question involving patients' rights raised in this case should have been whether the patients have a "legitimate expectation of privacy" in the contents of their medical records. This Court held in *California v. Ciraolo*, __ U.S. __, 106 S.Ct. 1809 (1986), that the determination of whether an individual has a "constitutionally protected reasonable expectation of privacy" entails a two-part test: (1) the individual must manifest a subjective expectation of privacy in the object of the challenged search; and (2) society must be willing to recognize that expectation as legitimate. 106 S.Ct. at 1811.

Petitioner Wolin, like most medical patients, had a subjective expectation that his medical records would remain

---

6 The question of a patient's property interest in medical records appears to be a novel issue in the case law. In the only case found by Petitioner that directly addresses the issue, the court held that patients have a property interest in the information contained in their medical treatment records. *Pyramid Life Insurance Co. v. Masonic Hospital Ass'n of Payne County*, 191 F. Supp. 51, 54 (W.D. Ok. 1961).

private. Petitioner did not, after all, entrust his medical records to the public librarian; he instead gave them to a doctor who, under the laws and public policy of the State of Texas, has a legal obligation to keep the information confidential. Tex. Rev. Civ. Stat. Ann. art. 4495b § 5.08(b) (Vernon Supp. 1987). Petitioner, and the other patients of Dr. Burzynski, thus met the first prong of *Ciraolo*.

The second prong of *Ciraolo* is also satisfied in this case because society certainly recognizes that a person's expectation of privacy in medical records is legitimate. Under nationally accepted standards of behavior and under numerous state statutes, medical records are generally subject to control by the patients. Beginning with New York in 1828, most states have enacted statutes to protect the contents of medical records from disclosure. 8 Wigmore, *Evidence*, § 2380 n.5, at 819-27; and 1987 Supp. at 191 (McNaughton rev. 1961).[7] Federal statutes also recognize an individual's expectation of privacy in the contents of that

---

[7] The Court of Appeals incorrectly stated that the patients attempted to ground their asserted privacy interest in their medical records on the physician-patient privilege under Texas law. Concluding first that the matter involved a criminal investigation and then that no physician-patient privilege exists in federal common law, the Court of Appeals decided that the patients could not assert a legitimate expectation of privacy. The mere fact that a criminal investigation is involved, however, does not obliterate the patients' constitutional rights; in fact, constitutional rights are asserted more often in the context of criminal investigations than in any other context.

Further, the patients did not ground their asserted privacy interests exclusively on the physician-patient privilege under Texas law. The codification of this privilege under Texas law serves merely to underscore the importance society ascribes to the expectation of privacy between patient and physician.

person's medical records. The Freedom of Information Act, in fact, excludes all medical files from production because their disclosure "would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6).

Doctors, hospitals, and health care facilities each carefully handle and use medical records and must, if requested by the patient, forward those records to a physician, hospital, or health care facility of the patient's choice. Further, this Court has recognized that the constitutional right to privacy includes avoiding disclosure of personal matters about medical treatment. *Whalen v. Roe*, 429 U.S. 589, 599-600 (1977). Additionally, the Third Circuit has held unequivocably that individuals have a constitutional right to privacy in their medical records that can supercede the broad subpoena power of the government. *United States v. Westinghouse Electric Corp.*, 638 F.2d 570, 577 (3d Cir. 1980).

As this Court ruled in *Ex Parte Jackson*, 96 U.S. 727 (1878):

> The constitutional guarantee of the right of the people to be secure in their papers against unreasonable searches and seizures extends to their papers, thus closed against inspection, wherever they may be.

Id. at 733. Persons who place sealed items in the mail, like persons who entrust the safekeeping of their medical records to their doctor, expect that those documents will remain private. Their expectations do not depend on whether they have a possessory or ownership interest in the post office or the postal carrier's bag any more than the expectations of

individuals depend on whether the patient has a possessory or ownership interest in the doctor's office. Likewise, employees who bring closed luggage to the office prior to leaving on a trip reasonably expect privacy in the contents of that luggage. *O'Connor v. Ortega*, __ U.S. __, 107 S.Ct. 1492 (1987). As this Court held in a similar context:

> While whatever expectation of privacy the employee has in existence and the outward appearance of the luggage is affected by its presence in the work place, the employee's expectation of privacy in the *contents* of the luggage is not affected in the same way.

107 S.Ct. at 1497 (emphasis in original). Similarly, while patients may understand that the existence and outward appearance of their medical records lacks some privacy protection, they may reasonably expect that the contents of those records will remain private.

2. THE DECISION BY THE COURT OF APPEALS CONFLICTS WITH A DECISION BY THE U.S. COURT OF APPEALS FOR THE NINTH CIRCUIT IN *VONDERAHE V. HOWLAND*.

Contrary to the decision of the Court of Appeals below, the United States Court of Appeals for the Ninth Circuit has specifically found a fourth amendment violation where patients could suffer if their treatment is disrupted by seizure of their medical records under a general warrant. *VonderAhe v. Howland*, 508 F.2d 364 (9th Cir. 1974). In *VonderAhe*, the government searched a dentist's office for evidence pertaining to a tax investigation and seized hundreds of

patient records. As in the instant case, however, the government in *VonderAhe* knew exactly what information it needed and wanted and where the records were located. 508 F.2d at 370. The agents there, as the Ninth Circuit observed, could have sought the allegedly concealed records through other means and "in an orderly way without the sudden assault causing not only damage to the doctor's finances and prestige but undoubtedly inconvenience and possibly pain and suffering to the many patients who could not be treated for weeks due to the disruption." *Id.*[8]

---

[8] Unlike *VonderAhe*, the pain and suffering that befell Dr. Burzynski's patients as a result of the FDA's unwarranted and illegal seizure of their treatment records on his clinic were not mere possibilities, but fact. After his medical records were seized by the government, for example, Mr. William L. Cody, whose cancer had been in remission for some time, required further medical treatment. Dr. Burzynski, however, informed Mr. Cody that he could not be effectively treated without his medical records, which were in the hands of the government. Mr. Cody then attempted three times to reach Mr. Ewing by telephone, to no avail. In his next effort, Mr. Cody sought the assistance of the regional director of the FDA in Dallas, who informed him that the medical records were no longer the property of Mr. Cody, that they "belong[ed] to the court," and that Mr. Cody could not get them back. The regional director then stated, however, that if Mr. Cody wished to call Mr. Ewing the following day and mention his name, Mr. Ewing would make copies of the medical records for Mr. Cody. The following day, Mr. Cody called Mr.Ewing as directed and Mr. Ewing stated that Mr. Cody could not have copies of the records. When Mr. Cody informed him of his conversation with the regional director in Dallas, however, Ewing left the phone for a few minutes, ostensibly to find the records. He came back after only a short time, and told Mr. Cody that his records were not there. After Mr. Cody's testimony during the evidentiary hearing, his records were produced by the government when the hearing resumed the following day. (TR Vol. III, at B-23; Vol. XII, at VI-167). Some of Mr. Cody's medical records, however, are still missing. (TR Vol. VIII, at III-125).

The warrant executed by the government's agents in this case on July 17, 1985, clearly delegated unfettered discretion to the executing officers,[9] with no limitation as to the time frame to be covered in the medical records to be seized, and with no specific description as to which records were to be seized. While the affidavit behind the search warrant contained some definite information that could have been used to specify with particularity the records to be seized, that was not done.[10] The only guidance given to the officers

---

9 The warrant clearly authorizes more than a search and seizure of FDA-related records. Rather than delineating the precise nature of the offenses for which the search was authorized, the government impermissibly chose to reference a laundry-list of statutes without any basis or probable cause for doing so. Such general rummaging for evidence of a federal crime does not comport with constitutional search and seizure requirements. *See, e.g., In re Lafayette Academy*, 610 F.2d 1, 3-4 (1st Cir. 1979).

10 Based on information received from V.A. Randazzo and Rebecca A. Lecky, for example, the warrant could have instructed the officers to seize the treatment records of Donald D. Lecky, the specific insurance claims submitted by Dr. Burzynski with regard to this patient, any and all letters pertaining to insurance claims for treatment of this patient, and bills of lading from Purolator Courier Corporation regarding shipments between Lecky and Dr. Burzynski. App. D at pp. 53a - 58a. Similarly, based on the information received from Ann Skelley, the warrant could have instructed the officers to seize only the insurance records pertaining to Greg Talbot, and the shipping records dated September 19, September 25, and October 8, 1984. App. D at pp. 58a - 60a. With respect to the allegations by confidential informants that double billing and overbilling of insurance carriers was standard procedure, the warrant could have instructed the officers to seize those files in which both the patient billing records and insurance claims forms showed billings for antineoplaston treatments. App. D at pp. 60a - 61a. Further, based on the information in paragraph 13 of the affidavit regarding the "true home addresses" of patients who reside outside of Texas, the warrant could have instructed the officers to seize only those

executing the warrant in this case was that the records and "other property" to be seized "show that antineoplastons have been and are being distributed in interstate commerce in violation of Title 21, United States Code 331(d) and the injunction of this Court and that evidence violations of Title 18, United States Code, Sections 286, 287, 371, 401, 1001, 1341, and 1505."[11] App. D at p. 48a. This guidance, however, is not sufficiently particular to be constitutional.

---

files concealed from the FDA, i.e., the patient billing records and insurance records. App. D at p. 63a.

Finally, the affiant refers to information obtained from Purolator Courier Corporation in paragraphs 11 and 12 of the affidavit. App. D at pp. 61a - 63a. This information, however, revealed merely the account numbers that had been assigned to Dr. Burzynski and others, the route number on which Dr. Burzynski's medical clinic is located, the type of information typically contained on a Purolator bill of lading, and the total number of shipments made from one of the accounts identified on this particular route during 1984. The affiant then observed that "at least 36 shipments [were] made [via Purolator] between March 1 and April 24, 1985," and, without substantiation or an indication of any source, made the conclusory allegation that these shipments were "thought to be antineoplastons." App. D at p. 62a. These unsupported allegations, however, are absolutely insufficient to justify a warrant. *Nathanson v. United States*, 290 U.S. 41, 46-47 (1933). Furthermore, regardless of the sufficiency of this allegation, any warrant issued based solely on this factual allegation could, within the confines of the fourth amendment, at most direct the officers to look only at the specific shipping records for the period between March 1, and April 24, 1985.

[11] The government agent who signed the underlying affidavit unabashedly admitted that he wanted the criminal search warrant because he was looking for evidence that Dr. Burzynski was in violation of the district court's civil injunction. App. D at p. 64a. This evidence, however, as stated *infra*, could have been easily obtained by following the civil discovery process contemplated by the Federal Rules of Civil Procedure. App. D at p. 64a.

Further, as this Court has admonished, when a warrant authorizes a search and seizure of a person's papers, the government agents must also "take care to assure that [the search is] conducted in a manner that minimizes unwarranted intrusions upon privacy." *Andresen v. Maryland*, 427 U.S. 463, 482 n.11 (1976). The term "unreasonable" found in the proscriptions of the fourth amendment thus applies to the manner of execution of the search warrant as well as to the breadth of the warrant. Applying these standards, the warrant at issue obviously suffers from the same constitutional infirmities that were held to invalidate the warrant in *United States v. Abrams*, 615 F.2d 541, 544-45 (1st Cir. 1980). In *Abrams*, the search warrant authorized the seizure of:

> certain business and billing and medical records of patients of Drs. Abrams, London, Braun, and Abrams, London, and Associates, Inc. which show actual medical services performed and fraudulent services claimed to have been performed in a scheme to defraud the United States and to submit false Medicare and Medicaid claims for payments to the United States or its agents; in violation of Title 18, United States Code, Section 1001.

Id. at 546-47.

In executing the warrant in *Abrams*, all of the Medicare and Medicaid records in the doctors' offices were seized, along with medical records of approximately twenty non-Medicare-Medicaid patients. *Id.* at 542. The First Circuit affirmed suppression of the evidence because the warrant

failed to meet the requirement of particularity. The infirmities so obvious to the First Circuit, however, are precisely those ignored by the Fifth Circuit. As in *Abrams*, the warrant in this case was amorphously worded so as to result in an indiscriminate seizure of both relevant and irrelevant material.[12]

Further, the officer's discretion in this case, as in *Abrams*, was completely unfettered as to the time frame to be covered. Although the search warrant made no reference to any time frame, the government agent in charge of the seizure stated at the time of the seizure that he was interested in only the activities that had taken place since May of 1983 and thus agreed not to take any files lacking activity subsequent to May of 1983. (TR Vol. XIII, at VII-132, 134). He then changed his mind and seized all the records, but stated after the seizure that he would return the records that predated May 1983. (TR Vol. XIII, at VII-134, 136;

---

12 As a result of the general description in the search warrant in this case, the executing officers seized such items as: eleven four-drawer filing cabinets with billing records, patient records, and insurance claims; a folder of miscellaneous notes of a Mr. Frye; twelve computer printouts of patient names; one file labeled "Canadian Patients Response"; one file drawer of North American Consultants correspondence; one set of patient index cards from the office of Dr. Burzynski; and, from the desk of Dr. Burzynski, a TWX concerning an E. Ploch, a list of patients participating in TV programs, a letter from a Ms. Oldaker, a list of patients owed money, a memo of a phone call with a Ms. Axford, a list of patients to check out, and a folder with handwritten notation of "shipments to patients." App. D at pp. 49a - 50a. The executing officers, in fact, took treatment records of all patients ever seen by Dr. Burzynski since 1973, including many who were never treated for cancer. (TR Vol. X, at IV-65-67).

Vol. XI, at V-109). No records, however, have yet been returned.[13]

3. THE DECISION BELOW CONFLICTS WITH THIS COURT'S INSTRUCTION THAT LOWER COURTS MUST CONSCIENTIOUSLY REVIEW THE SUFFICIENCY OF AFFIDAVITS UPON WHICH WARRANTS ARE ISSUED.

In addition to their claim that the seizure of their medical records was "unreasonable," the patients challenged the seizure because the supporting affidavit was insufficient to establish the existence of probable cause. As this Court

---

[13] In fact, even several months after the seizure of the treatment records, the government had not yet prepared a list of the patients whose treatment records were in its possession that would enable the government, on short notice and if a medical emergency arose, to ascertain immediately whether it possessed certain records. (TR Vol. II, at A-132). Further, despite the obvious importance of the information contained in the medical treatment records, the government has refused to photocopy and return these records so that Dr. Burzynski may have immediate access to the originals; instead, Dr. Burzynski's access to these records was dependent upon his financial ability to photocopy the documents at his own expense with his machine taken to the offices of the FDA. (TR Vol. III, at B-44-47). The agent in charge testified that he would not copy the medical records at government expense because his counsel had told him it was not necessary. (TR Vol. III, at B-38). The purported advice of the government's counsel, however, is contrary to the government's actions in *Sovereign News Company v. United States*, 690 F.2d 569 (1st Cir. 1982) (government had returned all original records seized during obscenity investigation and had retained only copies); *United States v. Chapman*, 559 F.2d 402 (5th Cir. 1977) (court ordered return of original betting records; government retained only copies); *Shaffer v. Wilson*, 523 F.2d 174 (10th Cir. 1975), *cert. denied*, 427 U.S. 912 (1976) (original of clinical dental records, patient x-rays, and correspondence had been returned; government retained only copies).

noted in *Illinois v. Gates*, 462 U.S. 213 (1983), there are limits beyond which a magistrate may not venture in issuing a warrant:

> Sufficient information must be presented to the magistrate to allow that official to determine probable cause; his action cannot be a mere ratification of the bare conclusions of others. In order to ensure that such an abdication of the magistrate's duty does not occur, courts must continue to conscientiously review the sufficiency of affidavits on which warrants are issued.

Id. at 239. Unfortunately, both of the lower courts, as well as the magistrate, ignored these limits. Neither the district court nor the Court of Appeals reviewed the sufficiency of the affidavit in this case.[14]

Taken as a whole, the circumstances set forth in the affidavit failed to demonstrate a fair probability that evidence of a crime would be found in Dr. Burzynski's medical clinic

---

[14] The district court, in fact, expressly ruled that it was "not making a determination as to whether or not the search warrant was supported by probable cause." App. B at p. 37a. Despite the district court's failing, the Court of Appeals did not remand the matter for a determination of probable cause.

The Court of Appeals also did not "conscientiously review the sufficiency of [the] affidavit[]" itself. Instead, the Court of Appeals impermissibly shifted its burden of examining the affidavit onto the victims of the unlawful search and seizure. According to the Court of Appeals' ruling, if the victims fail to set forth specifically in their counterclaim each and every factual basis on which the trier of fact could find that probable cause was lacking, the warrant will be upheld. Through this holding, the Court of Appeals retroactively imposed upon the patients a burden of pleading specific facts that is not required under Rule 8(a) of the Federal Rules of Civil Procedure.

on July 17, 1985. The eight-page affidavit submitted to the magistrate in this case contained the following allegations: (1) there had been an unsolicited interstate shipment of antineoplastons to a former patient, Donald D. Lecky, some eight months earlier; (2) the mother of a Louisiana patient, Greg Talbot, sought reimbursement from her insurance company for freight charges some ten months earlier for "cancer medicine sent from Houston"; (3) according to "corroborated" hearsay, there was some double-billing and over-billing of insurance companies by Dr. Burzynski; (4) Dr. Burzynski had a Purolator Courier Corporation account and made interstate shipments during 1984 and 1985; and (5) according to "corroborated" hearsay, Dr. Burzynski's records had been altered to conceal true home addresses of patients who reside outside Texas. Further, the affiant made conclusory statements that the premises may contain shipments of antineoplastons addressed for interstate delivery.

The affiant recounted that Dr. Burzynski had accounts with Purolator Courier Corporation, and gave the total number of shipments made from one of the accounts during 1984. The affiant then observed that "at least 36 shipments were made [via Purolator] between March 1 and April 24, 1985." Without substantiation or any indication of source, the affiant then made the conclusory allegation that these shipments were "thought to be antineoplastons." As in *Nathanson v. United States*, 290 U.S. 41 (1933), this mere conclusory statement gives the magistrate virtually no basis at all for making a judgment regarding probable cause. The subsequent statement by the affiant, that he had "reason to

believe that there may be on the premises ... one or more shipments of antineoplastons, addressed to one or more persons outside the State of Texas, awaiting pickup" by Purolator, does not even reflect whether he indeed believed it, much less why. This allegation is thus fatal for lack of any supporting basis under the teachings of *Nathanson*.

Further, the information obtained regarding the situation involving the patient Lecky does not bolster these unsubstantiated conclusions. Assuming the truth of the alleged November 1984 interstate shipment of drugs, the incident was certainly not closely related to the time that the warrant was issued, and thus cannot justify a finding of probable cause in July 1985. *Sgro v. United States*, 287 U.S. 206, 210 (1932).[15]

Further, each time the affiant refers to confidential informants in his affidavit, he states that their information "has been corroborated." App. D at pp. 60a, 63a. The affiant, however, fails to state how, when, and by whom the corroboration was made. Further, while the veracity and basis of knowledge of persons supplying hearsay information are some of the circumstances a magistrate

---

[15] Staleness also defeats the use of the information regarding the patient Talbot to support probable cause for issuance of the warrant in July 1985. The affiant states that he was informed by Ann Skelley, an employee of an insurance company, that the mother of patient Greg Talbot submitted three Purolator invoices to the insurance company for payment. App. D at pp. 58a - 60a. Two of those three are not alleged to have any connection with Dr. Burzynski. The third, dated September 19, 1984, had a handwritten notation "cancer medicine sent from Houston -- Dr. Burzynski," but no indication as to who wrote the notation.

should consider when determining whether probable cause exists to support a warrant, *Illinois v. Gates*, 462 U.S. at 239, the affiant in this case did not give any information pertaining to the reliability or credibility of the informants.

Finally, the affiant admits quite candidly that he had no reason to believe that certain documents had been removed from the office premises and, further, that he had no knowledge of medications shipped by Dr. Burzynski other than antineoplastons. App. D at pp. 52a, 63a. These candid admissions demonstrate the emptiness of the affiant's suspicions: a lack of knowledge simply does not support a conclusion that no such knowledge is available.

Because both courts below ignored their obligation to review the affidavit underlying the search warrant, neither noticed that the affidavit completely failed to establish probable cause for the seizure of the medical records. To compound the error, the Court of Appeals went beyond the record and concluded, *sua sponte*, that "the seized medical records were relevant to all of [the] possible [criminal] violations [alleged in] the warrant." There is, however, simply no evidence in the record to support this conclusion; the only support for that conclusion is the bare unsupported argument made by the government's counsel before the Court of Appeals.

4. THE DECISION BELOW THAT THE FEDERAL AGENTS VIOLATED NO NORMS OF CLEARLY ESTABLISHED LAW WHEN THEY OBTAINED AND EXECUTED SEARCH WARRANTS USED TO SEIZE THE PATIENTS'

MEDICAL RECORDS CONFLICTS WITH THIS COURT'S TEST RECENTLY ENUNCIATED IN *ANDERSON V. CREIGHTON.*

When the Court of Appeals decided that the agents in this case were entitled to qualified immunity, it failed to apply the test recently enunciated by this Court in *Anderson v. Creighton*:

> [T]he determination whether it was objectively legally reasonable to conclude that a given search was supported by probable cause or exigent circumstances will often require examination of the information possessed by the searching officials.... The relevant question in this case, for example, is the objective (albeit fact-specific) question whether a reasonable officer could have believed Anderson's warrantless search to be lawful, in light of clearly established law and the information the searching officers possessed.

107 S.Ct. 3034, 3040 (1987).

At no point in the Court of Appeals' analysis of the patients' section 1983 claims against the individual government agents, however, did it analyze the underlying affidavit to ascertain whether probable cause supported the issuance of the search warrant. Rather than independently examining the affidavit to ascertain probable cause, the Court of Appeals merely observed that "the district court found no basis even to proceed with a hearing on the validity of the search warrant, much less to justify a finding that the warrant was not validly supported." The Court of Appeals,

however, "cannot excuse [its] own default by pointing to the greater incompetence of the [district court]." *Malley v. Briggs*, 475 U.S. 335, 340 n.9 (1986). The Court of Appeals' circular reasoning that the warrant was not overly broad because the documents seized were only those described in the warrant also fails to support its conclusion that the seizure of these specific documents was in accordance with, rather than in contravention of, clearly established law.

CONCLUSION

For these reasons, the Court should issue a writ of certiorari to review the judgment and opinion of the Fifth Circuit, reverse the judgment below, and remand this matter for further proceedings.

Respectfully submitted,

By: _____

STUART M. NELKIN
NELKIN & NELKIN
5417 Chaucer
P.O. Box 25303
Houston, Texas 77265

MARGARET A. HARRIS
NELKIN & NELKIN
5417 Chaucer
P.O. Box 25303
Houston, Texas 77265

Counsel for Petitioner

December 23, 1987

CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of December 1987, three copies of the Petition for Writ of Certiorari were mailed, postage pre-paid, to the Solicitor General, Department of Justice, Washington, D.C. 20530, and, separately, to Gerald C. Kell, Office of Consumer Litigation, Department of Justice, P.O. Box 386, Washington, D.C. 20044, counsel for the Respondent. I further certify that all parties required to be served have been served.

_____

STUART M. NELKIN
Counsel for Petitioner

APPENDIX A

UNITED STATES of America, Plaintiff-Counter Defendant-Appellee

v.

BURZYNSKI CANCER RESEARCH INSTITUTE, et al., Defendants-Counter Plaintiffs-Appellants

and

Janice Kuharzyk, and Other Patients of Dr. Stanislaw R. Burzynski, et al., Intervenors-Counter Plaintiffs-Appellants.

No. 86-2183.

United States Court of Appeals, Fifth Circuit.

June 25, 1987,

Appeals from the United States District Court for the Southern District of Texas.

Before RUBIN, RANDALL, and JOHNSON, Circuit Judges.

ALVIN B. RUBIN, Circuit Judge:

Armed with a search warrant, the government seized a doctor's patient-treatment records during an investigation to determine whether the doctor had violated criminal fraud statues and a criminal statute forbidding the interstate ship-

ment of drugs that had not been approved by the Food and Drug Administration. The doctor and some of the patients, as intervenors, sought to have the records returned and to obtain damages and other relief by filing a counterclaim in a previously pending civil action filed by the government to enjoin interstate distribution of the drug. The district court properly held that the doctor and his patients have failed to establish any basis entitling them to a hearing on the validity of the search warrant or any grounds for finding that the seizure of the records was unconstitutional. We therefore affirm its dismissal of all counterclaims regarding the seizure or continued government retention of documents from the doctor's offices. Because, however, in the absence of an opportunity to conduct discovery regarding their contention that the government had provided insurance companies with false and misleading information, the doctor and his patients have not had a chance to develop facts that may entitle them to injunctive relief on that score, we remand that counterclaim for further proceedings.

I.

In 1983, the United States sued Dr. Stanislaw R. Burzynski and the Burzynski Cancer Research Institute (together referred to as Dr. Burzynski) in this civil action seeking to enjoin them from violating the Federal Food, Drug, and Cosmetic Act[1] by interstate distribution of a product used in cancer chemotherapy, antineoplastons, on the ground that the antineoplastons were "new drugs" within

---

1 21 U.S.C. § 301, et seq. (1982).

the meaning of the Act,[2] and were being distributed without prior approval by the Food and Drug Administration. Dr. Burzynski manufactures the natural type of antineoplastons from urine, and synthetic forms, called antineoplastons 10, from various chemicals. The government also sought to enjoin the manufacture and distribution of antineoplastons on the ground that the drugs were adulterated within the meaning of the Act[3] because Dr. Burzynski's manufacturing methods, facilities, and controls did not comply with the FDA's current good manufacturing practice regulations. A number of Dr. Burzynski's patients were allowed to intervene. After a two-day hearing, the district court issued an injunction granting most of the relief sought by the government. It also directed Dr. Burzynski to bring his research and manufacturing facility into compliance with FDA's current good-manufacturing procedures, ordering the FDA in turn to act promptly on their submission for approval. The order, however, expressly allowed Dr. Burzynski to continue manufacturing and prescribing the drug in Texas. The court expressly retained continuing jurisdiction to enforce or modify its order.

Two years later, in July 1985, as part of a criminal investigation based on a referral from the FDA to the Department of Justice, the government applied for and obtained a warrant to search an office complex that, as the warrant stated, housed the administrative offices of Dr. Burzynski and the Burzynski Research Institute, Incorporated, a separate legal entity from Burzynski Cancer

---

2 21 U.S.C. § 321 (p).

3 21 U.S.C. § 351(a)(2)(B).

Research Institute, which had been a defendant in the civil action. The application for the warrant was supported by the affidavit of FDA Compliance Officer, Kenneth P. Ewing. Ewing stated that the application was based on FDA inspections and investigations of Dr. Burzynski and the Institute, information supplied by insurance companies that had received claims from Dr. Burzynski, information supplied by the surviving spouse of one of Dr. Burzynski's patients, and information supplied by confidential informants.

In terms set forth in full in the footnote,[4] the warrant authorized a search for and seizure of records and other property that reflected distribution of antineoplastons outside the State of Texas and other records that would show the antineoplastons had been and were being distributed in interstate commerce in violation of Title 21, United States Code 331(d), the court injunction, and Title 18, United States Code, Sections 286, 287, 371, 401, 1001, 1341, and 1505. During the search Dr. Burzynski's employees were allowed to take records to a commercial copying center to make copies. On the advice of his employees, Dr. Burzynski

---

[4] Records and other property, including antineoplastons, of Stanislaw R. Burzynski, M.D., Burzynski Research Institute, Incorporated, Cameron Frye, and North American Consultants, Limited, that reflect:
(a) distribution of antineoplastons outside the State of Texas;
(b) the true addresses of persons to whom antineoplastons have been and are being distributed;
(c) patient treatment, patient accounts, and patient billings; and
(d) insurance claims and receipt of insurance payments that show that antineoplastons have been and are being distributed in interstate commerce in violation of Title 21 United States Code, Sections 331(d) and the injunction of this Court and that evidence violations of Title 18, United States Code, Sections 286, 287, 371, 401, 1001, 1341, and 1505.

himself "decided to give away filing cabinets along with the records" in order to protect the records. Since the execution of the search warrant, Dr. Burzynski has been allowed to install a copying machine in the FDA offices in Houston where the seized patient treatment records are being held and has made copies of those treatment records that he desires.

After the warrant had been executed, Dr. Burzynski and the Burzynski Research Institute, Inc. filed a counterclaim in this civil action seeking damages, injunctive relief, and contempt orders against the government and certain FDA employees, including the FDA Compliance Officer Ewing, Sharyn Miller, an investigator who had assisted Ewing in executing the warrant, and other unknown agents of the FDA and the United States. Certain named patients of Dr. Burzynski were given leave to file their own counterclaim as intervenors and sought a temporary restraining order commanding return of the records and other emergency relief.

During a twelve-day hearing on the motion for a temporary restraining order and contempt ruling, Dr. Burzynski testified that he had continued to treat patients in Texas. Based on what some of them told him, he suspected that antineoplastons were supplied from the Institute to patients in other states, but he testified that he did not believe it would be possible to detect such shipments with certainty unless every one of the Institute's employees had "a spy on his back." After the hearing was completed, the district court denied all of the motions.

The government then responded to the counterclaims by

moving for their dismissal for failure to state a claim for which relief could be granted or, in the alternative, for summary judgment. In a brief order, which referred to the evidence adduced in the earlier hearing on the motion for a temporary restraining order, the court dismissed the counterclaims.

II.

Dr. Burzynski and the patients contend that the district court impermissibly consolidated the hearing on the motions for TRO, return of property, and contempt (the preliminary motions) with trial on the merits of their counterclaims. The simple fact is that no such consolidation occurred. At the close of the hearing on the preliminary motions, the district court orally denied those motions. Thereafter, the court entered a nine-page order setting forth its findings with respect to the preliminary motions and its legal basis for denying those motions. Subsequent to the hearing on the preliminary motions, the government filed its motion to dismiss for failure to state a claim or, alternatively, for summary judgment on all of the counterclaims. In an order separate from the order denying the preliminary motions, the district court dismissed the counterclaims.

The district court did state in the later order that, because the issues raised in the counterclaims "raise legal questions which were decided against the Defendants and Intervenors [Dr. Burzynski and the patients] in the hearing of October 23, 1985" (the hearing on the preliminary motions), it would not repeat its discussion of those issues. In other words, the district court simply elected not to restate in its dismissal

order legal analysis it had already set forth in its denial of the preliminary motions. In deciding, based on that legal analysis, to dismiss the counterclaims, the district court did not conduct a trial on the merits, much less impermissibly consolidate trial with the hearing on the preliminary motions.

The patients also attack the dismissal order as being "pithy to the point of being incomplete" and ask this court to vacate it and remand the case for further consideration. In support of that request, they rely on *Myers v. Gulf Oil Corporation*,[5] in which we held that a district court's explanation that the defendant should be granted summary judgment "because the Plaintiff had failed to state a claim on which relief can be granted" was insufficient to explain that court's reasoning. The patients' argument focuses on the length of the district court's dismissal order rather than on its content. Taken together, the two orders adequately present for our review both the actions taken by the district court and its reasons.

III. Claims for Monetary Relief

Dr. Burzynski and the patients seek monetary damages from the United States, FDA, FDA employees Ewing and Miller (both individually and in their official capacities), and unknown agents of the United States and the FDA. We discuss these claims separately.

A. Claims Against the Government

Neither the United States, its agencies, nor its officials acting in their official capacities, may be sued without the

---

5 731 F.2d 281, 283 (5th Cir. 1984).

United States' specific consent.[6] The Federal Tort Claims Act[7] permits certain claims to be asserted against the United States, as sovereign, and its agents but exacts the filing of an administrative claim for relief as a jurisdictional prerequisite to suit. No such claim has been filed. Therefore, the district court properly dismissed the damage claims against the United States, the FDA, and federal officials acting in their official capacities. Because the requirement of administrative review is a jurisdictional requisite, is would not have been appropriate merely to stay the suit until a claim could be filed, as Burzynski sought, once the issue was raised.[8]

B. Claims Against Individual Government Employees

In seeking monetary damages against the government employees as individuals, Dr. Burzynski and the patients asserted both common law tort claims and claims under the Constitution. All of the damages claims asserted against individual government employees related to and arose out of the application for and execution of the criminal search warrant for Dr. Burzynski's business premises, and all are barred by immunity doctrines.

1. Waiver of Immunity Defenses

Dr. Burzynski and the patients contend that the government cannot rely on immunity defenses for the individuals

---

6 *United States v. Sherwood*, 312 U.S. 584, 586, 61 S.Ct. 767, 769, 85 L.Ed. 1058 (1941); *Zapata v. Smith*, 437 F.2d 1024, 1025 (5th Cir.1971); *Carter v. Seamans*, 411 F.2d 767, 770 (5th Cir.1969), *cert. denied*, 397 U.S. 941, 90 S.Ct. 953, 25 L.Ed.2d 121 (1970).

7 28 U.S.C. § 2671, et seq. (1982).

8 *Gregory v. Mitchell*, 634 F.2d 199, 203–04 (5th Cir.1981).

named as defendants because such affirmative defenses may not be raised by means of a motion to dismiss or for summary judgment. The circuit courts disagree whether the affirmative defenses listed in Fed.R.Civ.P. 8(c) must be asserted in the defendant's answer or may be raised for the first time in a motion to dismiss or other dispositive motion.[9] In *Funding Systems Leasing Corp. v. Pugh,* a panel of this court stated that a defendant may raise an affirmative defense by a motion for summary judgment only when that motion "is the initial pleading tendered by [the] defendant."[10] Although the rule quoted above suggests that any prior pleading will defeat the defendant's right to raise an affirmative defense in a summary judgment motion, in the context of the decision as a whole it becomes apparent that the *Funding Systems* opinion was referring only to pleadings responsive to the substantive issues charged. The *Funding Systems* decision itself specifically noted that the defendant in that case had failed to allege his affirmative defense in any "responsive pleading."[11] The decision, therefore, did not address the issue whether prior pleadings that are unresponsive to the substance of the allegations should preclude the possibility of raising affirmative defenses in a subsequent responsive pleading. Because no other panel of this court has had occasion to apply the rule that *Funding Systems* sets forth, the proper interpretation of the rule remains unde-

---

9 *See* C. Wright and A. Miller, *Federal Practice and Procedure* § 1277, at 328–29 (1969). *Compare Williams v. Murdoch,* 330 F.2d 745 (3d Cir.1964); *Continental Collieries, Inc. v. Shober,* 130 F.2d 631 (3d Cir.1942) *with Eberle v. Sinclair Prairie Oil Co.,* 35 F.Supp. 296 (E.D.Okla.1940), *aff'd,* 120 F.2d 746 (10th Cir.1941).

10 530 F.2d 91, 96 (5th Cir.1976).

11 *Id.*

cided, and we adopt what we believe to be the most principled interpretation of the standard: An affirmative defense may be raised on a motion for summary judgment only if that motion is the first pleading responsive to the substance of the allegations.

Although in this case the government filed a brief memorandum in opposition to Dr. Burzynski's original counterclaim and several preliminary motions before filing its motion to dismiss or for summary judgment, none of those filings is a responsive "initial pleading" within the meaning of *Funding Systems*. The government's initial memorandum is not a "pleading" and did not purport to respond to the substantive charges of the counter-claim. It presented only a legal analysis of the procedural posture of the case, raising issues about whether the counterclaim was filed in accordance with the Federal Rules of Civil Procedure and about the propriety of using civil counterclaims as a means of hampering criminal investigations. Similarly, the government's ensuing motions—which are "pleadings" within the meaning of the Rules—were not responsive to the substance of the counterclaims, but sought only to preserve counter-defendants' rights pending preparation of an answer or dispositive motion. Because the government, therefore, set forth its affirmative argument in its first responsive pleading, it has preserved its immunity defenses.

2. Common Law Tort Claims

Federal employees are absolutely immune from common law tort suits for damages arising out of the performance of either mandatory or discretionary acts that are, as the

Supreme Court stated in Barr v. Matteo, "within the outer perimeter of the [employees'] line of duty."[12] This immunity extends even to allegedly malicious acts.[13]

It is difficult to sort out the common law claims of Dr. Burzynski and the patients from their constitutional claims. Reading the counterclaims as broadly as possible, however, it appears that, with respect to the application for and execution of the search warrant, Dr. Burzynski asserted common law claims for abuse of process and for some type of tortious interference with his relationship with his patients, while the patients asserted a common law claim for abuse of process.

Ewing's duties as a compliance officer with FDA included reviewing investigative records of FDA and other evidence gathered by FDA to determine whether there were apparent violations of the FDC Act or other laws, making recommendations for appropriate civil or criminal legal action, conducting investigations, and collecting of information and samples. FDA compliance officers and investigators also are required, in conjunction with a United States Marshal, to execute criminal search warrants. Moreover, Ewing was the person within FDA chiefly responsible for the investigation of Dr. Burzynski.

Acting upon information gathered in the course of previous

---

[12] *Barr v. Matteo*, 360 U.S. 564, 575, 79 S.Ct. 1335, 1341, 3 L.Ed.2d 1434 (1959). *Accord Evans v. Wright*, 582 F.2d 20, 21 (5th Cir.1978).

[13] *Barr*, 360 U.S. at 575, 79 S.Ct. 1341; *Norton v. McShane*, 332 F.2d 855, 858 (5th Cir.1964), *cert. denied*, 380 U.S. 981, 85 S.Ct. 1345, 14 L.Ed.2d 274 (1965).

FDA investigations of Dr. Burzynski and others, and upon information supplied to him by named individuals and confidential informants, Ewing, Miller, and other federal employees pursued a new investigation of Dr. Burzynski to determine if Dr. Burzynski had violated the Act and other federal criminal statutes by failing to adhere to the requirements of the permanent injunction entered by the district court in May 1983. That investigation included the application for and execution of the criminal search warrant.

The activities of Ewing, Miller, and the other federal employees with respect to the search warrant were clearly within the scope of their duties. Therefore, they are absolutely immune from suit for the common law torts allegedly committed in connection with the search warrant, and dismissal of the damage claims based on those alleged torts was proper.

3. Constitutional Tort Claims

In *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics,*[14] the Supreme Court held that federal officers who, acting under color of their federal authority, but without a warrant, entered and searched the plaintiff's apartment and arrested him, could be personally sued for monetary damages for deprivation of the plaintiff's rights under the fourth amendment. The holding of *Bivens* was extended to deprivations of fifth amendment due process rights in *Butz v. Economou,*[15] to violations of the right to equal protection as embodied in the fifth amendment in *Davis*

14 403 U.S. 388, 91 S.Ct. 1999, 29 L.Ed.2d 619 (1971).
15 438 U.S. 478, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978).

v. Passman,[16] and to the eighth amendment's prohibition against cruel and unusual punishment in *Carlson v. Green.*[17]

Shortly after its recognition of a right of action for constitutional torts under *Bivens*, the Supreme Court began to develop the defense of qualified immunity to protect federal employees against liability for, and the burden of defending themselves against, alleged violations of constitutional rights. As first formulated in *Butz v. Economou,* qualified immunity had both an objective and subjective element: the federal official was entitled to immunity if there were reasonable grounds to believe that the challenged conduct did not violate a constitutional right (the objective element) and the official undertook the challenged conduct in a good-faith belief that the conduct was valid (the subjective element).[18]

On further consideration, however, the Court in *Harlow v. Fitzgerald* stated, "[t]he subjective element of the good-faith defense frequently has proved incompatible with our admonition in *Butz* that insubstantial claims should not proceed to trial."[19] Therefore, the Court eliminated the subjective element of the qualified immunity defense. Government officials performing discretionary functions, it held, are shielded from liability for civil damages whenever their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would

---

16 442 U.S. 228, 99 S.Ct. 2264, 60 L.Ed.2d 846 (1979).

17 446 U.S. 14, 100 S.Ct. 1468, 64 L.Ed.2d 15 (1980).

18 438 U.S. at 495–98, 507, 98 S.Ct. at 2905–07, 2911.

19 *Harlow v. Fitzgerald*, 457 U.S. 800, 815–16, 102 S.Ct. 2727, 2737, 73 L.Ed.2d 396 (1982).

have known.[20]

Reading Dr. Burzynski's counterclaim most broadly, it appears to allege that Ewing violated the fourth amendment by obtaining the criminal search warrant for Dr. Burzynski's business premises "to accomplish purposes outside the proper scope of a search warrant," i.e., "for the apparent ulterior purpose of forcing [Dr. Burzynski] out of business." The government contends, however, that the warrant was issued by an independent judicial officer, the United States Magistrate, and that under this court's decision in *Jureczki v. City of Seabrook, Texas*,[21] "[a] judge's determination of probable cause breaks the chain of causation and insulates the initiating party from liability."[22] Dr. Burzynski counters by correctly pointing out that the Supreme Court rejected the rationale underlying that broadly-stated rule in *Malley v. Briggs*.[23]

In *Malley*, the Court held that an officer may not rely on the judgment of a judicial officer in finding that probable cause exists if "a reasonably well-trained officer would have known that his affidavit failed to establish probable cause

---

[20] 457 U.S. at 817–18, 102 S.Ct. at 2737–38. *See also David v. Scherer*, 468 U.S. 183, 104 S.Ct. 3012, 3018, 82 L.Ed.2d 139 (1984); *Mitchell v. Forsyth*, 472 U.S. 511, 535 n. 12, 105 S.Ct. 2806, 2820 n. 12, 86 L.Ed.2d 411 (1985); *Saladana v. Garza*, 684 F.2d 1159, 1163 (5th Cir.1982), *cert. denied*, 460 U.S. 1012, 103 S.Ct. 1253, 75 L.Ed.2d 481 (1983).

[21] 760 F.2d 666, 668 (5th Cir.1985), *cert. denied*, —U.S.—, 106 S.Ct. 1261, 89 L.Ed.2d 511 (1986).

[22] *Id.* (citing *Smith v. Gonzales*, 670 F2d 522, 526 (5th Cir.), *cert. denied*, 459 U.S. 1137, 103 S.Ct. 772, 74 L.Ed.2d 984 (1982)).

[23] 475 U.S. 335, —, 106 S.Ct. 1092, 1098–99, 89 L.Ed.2d 271 (1986).

and that he should not have applied for the warrant."[24] This holding, however, does not signal a retreat from the principle that, to give rise to liability, the actions of a public official must be objectively unreasonable in the light of clearly established law. Malice, therefore, remains "irrelevant in obtaining a warrant where probable cause exists."[25]

Dr. Burzynski's counterclaim alleges no misstatements or omissions in Ewing's affidavit that would have obviated probable cause if corrected. Indeed Dr. Burzynski in effect supported its correctness by testifying that, based on the affidavit as well as his own independent suspicions, he suspected that antineoplastons were being transported out of Texas, that the Institute has been obliged to refund hundreds of insurance overpayments resulting from insurance companies being billed for services already paid for by patients, and that on at least one occasion an insurance claim was submitted for an office visit when the patient did not actually come to the Institute.

Dr. Burzynski's counterclaim does contain an allegation that the search warrant "was not supported by affidavits and evidence sufficient to establish probable cause." Based on no more than this unsupported charge, and despite the admonition of the Supreme Court in *Franks v. Delaware*[26] that to mandate an evidentiary hearing such a charge must also assert deliberate falsehood or reckless disregard for truth and

---

24 *Id.* (footnote omitted).

25 *Jureczki*, 760 F.2d at 668.

26 438 U.S. 154, 171–72, 98 S.Ct. 2674, 2684, 57 L.Ed.2d 667 (1978).

must be accompanied by an offer of proof, the district court allowed a lengthy cross-examination of Ewing regarding his affidavit. Nonetheless, the district court found no basis even to proceed with a hearing on the validity of the search warrant, much less to justify a finding that the warrant was not validly supported. In this circuit, once a government employee has asserted qualified immunity and established that the allegedly tortious acts were undertaken within the scope of his discretionary authority, the burden shifts to the party seeking damages to show that qualified immunity does not bar recovery.[27] Dr. Burzynski has failed to suggest any factual basis upon which a trier of fact could find that probable cause was lacking or that Agent Ewing's action in seeking the search warrant was objectively unreasonable. Therefore, the individual defendants were entitled to have those charges against them dismissed.

In addition, both Dr. Burzynski and the patients asserted constitutional claims with respect to the government employees' execution of the warrant. Both Dr. Burzynski and the patients challenged the warrant as overly broad (not properly limited in scope), Dr. Burzynski alleging a fourth amendment violation and the patients a fifth amendment violation. Additionally, the patients alleged that seizure of their medical records was unreasonable, in violation of the fourth amendment, and infringed their constitutional rights to privacy, to life, and to obtain medical treatment. Again, these

---

[27] See *Saldana v. Garza*, 684 F.2d at 1163 n. 14 (citing *Garris v. Rowland*, 678 F.2d 1264, 1271 (5th Cir.1982); *Rheaume v. Tex. Dept. of Public Safety*, 666 F.2d 925, 930 (5th Cir.1982); *United Carolina Bank v. Board of Regents*, 665 F.2d 553, 562 (5th Cir.1982); *Baker v. Norman*, 651 F.2d 1107, 1121 (5th Cir. 1981)).

claims could survive the government defenses of qualified immunity only if Dr. Burzynski and the patients demonstrated a reasonable basis to believe that the execution of the search warrant violated "clearly established law."[28] They simply failed to do so. According to the counter-claimants' own witnesses, the documents seized were only those described in the warrant. Since the seizure of these specific documents was thus authorized, the seizure was in accord with, rather than in contravention of, clearly established law.

The patients also assert that seizure of their treatment records, which belonged to Dr. Burzynski or the Institute and were in the possession of Institute, invaded their right to privacy. That they have a privacy interest in such documents[29] does not establish the immunity of the documents from seizure. The patients do not cite a single case in which seizure of documents authorized by a warrant has been found to be an unconstitutional invasion of privacy. The absence of such citations is not surprising since a warrant issued upon "[p]rior review by a neutral and detached magistrate is the time-tested means of effectuating Fourth Amendment rights."[30] In any event, seizure of the patients' treatment records pursuant to a warrant did not violate clearly established law so as to subject the government agents to individual liability.

The patients also assert that seizure of their treatment records deprived them of their right to life and to medical

---

28 *Harlow v. Fitzgerald*, 457 U.S. at 818, 102 S.Ct. at 2738.

29 See *In re Search Warrant*, 810 F.2d 67, 71 (3d Cir. 1987).

30 *United States v. United States District Court, E.D. Mich.*, 407 U.S. 297, 318, 92 S.Ct. 2125, 2137, 32 L.Ed.2d 752 (1972).

treatment. This claim was unsupported by factual allegations creating any basis to believe that the treatment of patients would be substantially hindered. All of the parties agree that the records are available for copying. As the district court determined below, the patients have shown no basis to believe that "an opportunity would not be made available to [Dr. Burzynski] to secure a copy of those documents in sufficient time to treat his patients effectively...."

In sum, the federal employees involved in obtaining the warrant for the search of the business premises occupied by Dr. Burzynski and in executing that warrant followed established constitutional procedures. They violated no norms of clearly established law. As federal agents performing discretionary functions within the scope of their duties, they were entitled to qualified immunity shielding them from liability for their acts. The district court's dismissal of the constitutional claims against the federal employees was therefore proper.

IV. Injunctive Relief

The counterclaims requested injunctions requiring return of the records seized pursuant to the search warrant, prohibiting use of the seized records by the government, prohibiting government contact with patients and their insurance carriers, prohibiting the government from interfering with Dr. Burzynski's treatment of the patients with antineoplastons, and prohibiting the government from disseminating allegedly false or misleading information regarding antineoplastons.

A. Return of the Seized Records

Fed.R.Crim.Proc. 41(e) provides the avenue by which a person may obtain return of property seized by the government. Because neither Dr. Burzynski nor the patients stated any basis for a finding that the records were illegally seized and the patients did not even allege a basis for finding that were entitled to lawful possession of the records, the district court was required to dismiss the injunctive claims for return of the records, whether under Rule 41(e) or its general equity jurisdiction.

Both the patients and Dr. Burzynski acknowledged that the medical records were seized from Dr. Burzynski's business premises. On appeal, the patients state that their "property interest [is] in the information contained in their medical treatment records." Thus, the patients' own allegations demonstrate that they were not "entitled to lawful possession of the property" which was seized and, therefore, that they did not have standing to seek return of the seized records.

Since the medical records were seized from the Dr. Burzynski's business premises, the patients would have had standing to challenge the search and seizure only if they had a "legitimate expectation of privacy in [those] premises," a business belonging to others.[31] Even if the seized medical records had been the property of the patients, "[t]he fact that [their] property became the 'target' of the search is irrelevant."[32]

---

31 *Dickens v. Lewis*, 750 F.2d 1251, 1254 (5th Cir. 1984).

32 *Id.* (citing *Rakas v. Illinois*, 439 U.S. 128, 99 S.Ct. 421, 426-27, 58 L.Ed.2d 387 (1978)).

The patients attempt to ground their asserted privacy interest in their medical records on a physician-patient privilege as codified in Texas state law, Tex. Rev. Civ. Stat. Ann. art. 4495B § 5.08(b) (Vernon Supp.1985). The seizure of the records, however, took place pursuant to a search warrant as part of a criminal investigation, and was therefore exempt from the Texas shield. In the context of federal criminal proceedings, no physician-patient privilege exists.[33] Therefore the patients had no legitimate expectation of privacy in the records maintained by Dr. Burzynski that could be asserted against the search warrant and no standing to seek the return of the records.

Even if the patients had alleged circumstances sufficient to afford them standing to seek return of the medical records, they alleged no basis on which the district court could have found the seizure of the records unlawful. The patients argue that their sole challenge to the warrant authorizing the seizure was to the face of the warrant, not the supporting affidavit. Yet the only specific deficiency alleged by the patients was that the warrant authorized the seizure of virtually all medical records at the Institute while the supporting affidavit stated that patients' true home addresses were recorded only on patient billing and insurance records. The patients' argument rested on the premise that the only purpose of the warrant was to "ascertain evidence of interstate shipment of antineoplastons." The warrant was sought, however, to authorize the seizure of evidence of numerous criminal offenses in

---

[33] *United States v. Meagher*, 531 F.2d 752, 753 (5th Cir.), *cert. denied*, 429 U.S. 853, 97 S.Ct. 146, 50 L.Ed.2d 128 (1976); *United States v. Mancuso*, 444 F.2d 691, 694-95 (5th Cir.1971).

addition to interstate distribution of antineoplastons. Since the seized medical records were relevant to all of those possible violations the warrant was facially valid, and the patients stated no basis for the district court to find seizure of the medical records unlawful, a prerequisite to mandating their return.[34]

Unlike the patients, Dr. Burzynski did attack the affidavit supporting the warrant. However, he neither alleged nor proved a single fact on which the district court could have found the affidavit deficient and the resulting warrant and seizure unlawful.

B. Use of the Seized Records

Both the patients and Dr. Burzynski seek to enjoin the government from providing the records seized pursuant to the search warrant to any other agents or agencies of the United States Government or to any commercial entity or to any other entity or person. While not alleging any basis to believe that the government had made improper use of the seized records or was likely to do so, Dr. Burzynski and the patients sought an injunction that, if granted, would have totally prevented the government from pursuing its criminal investigation of Dr. Burzynski insofar as the seized records constituted evidence of crimes or suggested avenues of investigation.

As an incident to the separation of powers founded in the

---

[34] Fed.R.Crim.P. 41(e).

Constitution, "the courts are not to interfere with the free exercise of the discretionary powers of the attorneys of the United States in their control over criminal prosecutions."[35] Furthermore, to the extent that an injunction against providing the seized documents to "any other person or entity" would prohibit presenting the documents to a grand jury, such an injunction would would improperly interfere with the mission of the grand jury which "must be free to pursue its investigations unhindered by external influence or supervision...."[36] "The Fifth Amendment guarantees that no civilian may be brought to trial for an infamous crime 'unless on a presentment or indictment of a Grand Jury.' This constitutional guarantee presupposes an investigative body 'acting independently of either prosecuting attorney or judge....'"[37]

Since neither Dr. Burzynski nor the patients alleged even one arguably improper use of the seized records, the district court had no proper choice but to dismiss the requests to enjoin use of the seized records by the government.

C. Communications with Patients or Insurance Companies

Similarly, the requests of Dr. Burzynski and the patients that the government be enjoined from communicating with Dr. Burzynski's present and former patients and their insurance carriers, would, if granted, have impeded or

---

35 *United States v. Cox*, 342 F.2d 167, 171 (5th Cir.) (en banc), *cert. denied*, 381 U.S. 935, 85 S.Ct. 1767 (1965).

36 *United States v. Dionisio*, 410 U.S. 1, 17, 93 S.Ct. 764, 773, 35 L.Ed.2d 67 (1973).

37 *Id.* at 16, 93 S.Ct. at 772 (quoting *Stirone v. United States*, 361 U.S. 212, 218, 80 S.Ct. 270, 273, 4 L.Ed.2d 252 (1960)).

totally frustrated the government's ability to pursue its investigation of, among other things, interstate distribution of antineoplastons, fraudulent over-billing and double-billing of insurance companies, and false statements to the government. Such an injunction would obviously have interfered with "the free exercise of the discretionary powers of the attorneys of the United States in their control over criminal prosecutions."[38]

D. Alleged Interference with Treatment of Patients and Dissemination of False Information

Dr. Burzynski and the patients also asked the district court to enjoin the government from interfering with Dr. Burzynski's treatment of the patients with antineoplastons, both intrastate and interstate.

The interference alleged included the seizure of patient records pursuant to the search warrant, the refusal of the FDA to grant investigational new drug status (IND) to the form of antineoplastons Dr. Burzynski is currently using, and the dissemination of false or misleading information about Dr. Burzynski and his treatment to insurance companies and current or prospective patients. Many of these claims are patently groundless. Just as the allegations of unlawful seizure of patient records cannot support injunctive relief requiring return of the seized records, they cannot form a cognizable basis for claiming that the government has or would interfere impermissibly with Dr. Burzynski's treatment of patients solely within the State of Texas. There simply has been no genuine issue of such a threat raised.

---

38 *United States v. Cox*, 342 F.2d at 171.

Similarly, neither Dr. Burzynski nor his patients have alleged facts suggesting that the FDA has acted improperly by denying antineoplaston A10 IND status. Although, in his brief before this court, Dr. Burzynski contends that he has never argued that he is entitled to IND status for his new drug but only that the FDA has treated his application differently than other IND applications, the language of his counterclaims belie that assertion. In his countercomplaint, Dr. Burzynski asserted that "Dr. Burzynski's patients will be irreparably harmed if this Court [the district court] fails to require the FDA to grant IND status to the Antineoplaston A10 compound...in that many patients who could be helped by the use of antineoplastons will be denied their Constitutional right of access to Dr. Burzynski's treatment...." The district court, therefore, construed his counterclaim correctly.

Dr. Burzynski's own testimony demonstrates that the FDA notified him in February 1984 that it found deficiencies in his IND application and required additional data. He candidly admits that he has neither provided the data requested nor explained to the FDA his reasons for considering that data unnecessary. Thus, he has failed to make a good faith effort to obtain an IND or to exhaust his administrative remedies. His claim for injunctive relief with respect to the IND was, therefore, properly dismissed.[39]

The patients indirectly challenge FDA's action with respect to the IND, alleging that their "constitutional right to travel

---

[39] *See Rutherford v. American Medical Association*, 379 F.2d 641 (7th Cir. 1967), *cert. denied*, 389 U.S. 1043, 89 S.Ct. 787, 19 L.Ed.2d 835 (1968).

freely between the states...is being infringed by the Government and its agents through their continued refusal to allow the interstate distribution and shipment of antineoplastons." Because Dr. Burzynski and his patients have failed to allege facts suggesting that IND status was improperly withheld, this claim was also dismissed properly. Moreover, to the extent that the patients' counterclaim can be construed as a challenge to the authority of the FDA to bar interstate distribution of unapproved drugs, the claim is frivolous.[40]

The patients' separate claim for injunctive relief against interference with interstate distribution of antineoplastons based on the asserted "constitutional right to obtain medical treatment that is encompassed by their right to privacy," was also unsupportable. The patients asserted that they should be free to obtain antineoplastons interstate because of "the unavailability of any other treatment that would be effective in treating their cancer." Similar claims were raised and rejected in *United States v. Rutherford*.[41]

As in the present case, the plaintiffs in *Rutherford* were cancer patients, alleged to be terminally ill, desiring treatment with an unapproved drug, and arguing that the restrictions on interstate distribution of new drugs imposed by the Act should not be allowed to interfere with their access to the drug. The Supreme Court rejected the patients' claims. The Court agreed with FDA that the new drug approval provisions of the Food, Drug, and Cosmetic Act specifically applied to the situation presented.

---

40 *See United States v. Lebman*, 464 F.2d 68, 73–74 (5th Cir.), *cert. denied*, 409 U.S. 950, 93 S.Ct. 271, 34 L.Ed.2d 220 (1972).

41 442 U.S. 544, 99 S.Ct. 2470, 61 L.Ed.2d 68 (1979).

In one respect, however, the fact that Dr. Burzynski and his patients were denied any opportunity for discovery has unfairly prejudiced their opportunity to allege facts in support of counterclaims that may entitle them to relief. The district court found that at least two statements made by Ewing in response to inquiries about Dr. Burzynski and his treatment were "near to inappropriate," exceeded "his duties and responsibilities as an officer of the FDA," and misled his audience by asserting, as established fact, charges still subject to investigation. The district court also noted that, by showing that such statements were made to at least one insurance company, Dr. Burzynski and his patients demonstrated that "the above conduct has had an impact on their ability to treat patients because over fifty percent of [the Institute's] income is derived from insurance payments." Whether additional examples of such questionable conduct exist and, if so, in numbers justifying injunctive relief can only be discerned through discovery. The claim seeking an injunction to stop the government from disseminating false or misleading information to outside parties, therefore, should not have been dismissed until Dr. Burzynski and his patients had an opportunity to discover the scope of the problem and to provide evidence that an injunction is necessary.

Of course, nothing in this opinion should be construed as suggesting that the FDA acted improperly by expressing its position with regard to the status of antineoplastons, i.e., that they are drugs that may not lawfully be introduced into interstate commerce because they are not approved by the FDA or the subject of an acceptable IND. Such information

is not false, misleading, or inaccurate.

The FDA also cannot be required to communicate what the patients view as "favorable" information. According to Dr. Burzynski and some of his patients, relevant "favorable information" is that antineoplaston therapy has proved beneficial to some cancer patients. The views of Dr. Burzynski and his patients, however, do not constitute "favorable" information upon which the FDA may properly rely. "[W]hen the subject of investigation is the existence of cancer, the personal testimony of the lay sufferer is entitled to no weight...."[42] Furthermore, as the Supreme Court found in Weinberger v. Hynson, Westcott and Dunning, Inc.,[43]:

> [FDA's] strict and demanding standards, barring anecdotal evidence indicting that doctors "believe" in the efficacy of a drug, are amply justified by the legislative history [of the Food, Drug, and Cosmetic Act]. The hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.

V. The Civil Contempt Claim Against the Government and its Employees

The same conduct by the government and its employees alleged as the basis for the damages and injunctive claims of Dr. Burzynski and the patients formed the basis of their

---

42 *United States v. Hoxey Cancer Clinic*, 198 F.2d 273, 280 (5th Cir. 1952), *cert. denied*, 346 U.S. 897, 74 S.Ct. 220, 98 L.Ed. 398 (1953).

43 412 U.S. 609, 619, 93 S.Ct. 2469, 2478, 37 L.Ed.2d 207 (1973) (footnote omitted).

requests to hold the government and its employees in civil contempt. Dr. Burzynski and the patients apparently do not appeal from the dismissal of their civil contempt claims. Their briefs to this court assign no error to the dismissal of those claims. But, even if they do appeal this ruling, the requests for a finding of civil contempt were also without foundation, and the district court's dismissal of those claims was proper.

The permanent injunction, of which the government and its employees were alleged to be in contempt, imposed no restrictions or obligations on the government or its employees, except that FDA was directed to review, evaluate, and appraise the manufacturing practices of the Burzynski Research Institute and promptly advise Dr. Burzynski of any violations of current good manufacturing practices. Although neither Dr. Burzynski nor the patients raised that issue in their counterclaims as a basis for a contempt citation or any other relief, the issue was raised at the hearing on Dr. Burzynski's motion for a temporary restraining order. However, as the record shows, FDA has advised Dr. Burzynski of its position with respect to his manufacturing practices, and so is in compliance with its obligations under the permanent injunction.

VI.

The patients who appear in this suit are in a critical plight. They seek any treatment that offers them the slightest hope for they think it is better to exhaust any possibility than to resign themselves to a fate that seems otherwise certain. The FDA has been assigned the duty of protecting such desperate

persons from deception, abuse, and exploitation and of assuring that the treatment they are given is safe and effective. It cannot perform these tasks if those professing to offer new cures refuse to work with the system and obey the law, whether their motives be noble or ill. This court, therefore, must not allow sympathy for the plight of persons suffering from cancer to cause us to interfere hastily with the mission of FDA or to distract us from our duty to uphold the law.

For the reasons given, the judgment of the district court is AFFIRMED in part, REVERSED in part, and REMANDED for further proceedings consistent with this opinion.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA,	§	
Plaintiff,	§	
V.	§	C.A. NO. H-83-2069
BURZYNSKI CANCER RESEARCH INSTITUTE, ET AL.,	§	
Defendants.	§	

ORDER

On October 2, 1985, the Court was presented an Application for a Temporary Restraining Order, a Motion to show cause why the Government should not be held in contempt, and a Motion for Return of Property filed by Defendants (Burzynski Research Institute and Dr. Stanislaw R. Burzynski) and Intervenors (Juanice Kuharzyk, Ronald G. Wolin, Richard A. Sharp, William L. Cody, Lilian Shore, and Ellen E. Trocchio). For the reasons cited below, the Court Denied the above Motions.

On October 23, 1985, after a four week hearing, the Court entered an Order denying the Defendants' Application for a Temporary Restraining Order, Motion to Show Cause Why the government (FDA) should not be Held in contempt, and Motion for Return of Property. The Court also denied Inter-

venors' Motion for Return of Property. With regard to the temporary Restraining Order, the Defendants raised four grounds:[1] 1) that the FDA wrongfully interfered with insurance payments for cancer treatment of patients of Dr. Burzynski; 2) that the FDA exercised bad faith in processing (or failing to process) Defendants' Investigational New Drug (IND) Application and Good Manufacturing Practices (GMP) Application; 3) that the FDA maliciously distributed false and misleading information regarding antineoplaston A and the Burzynski Research Institute to Patients, Insurance Companies and other third parties; and 4) that the FDA maliciously and illegally seized voluminous patient treatment, insurance, and financial records from Dr. Burzynski.

Pursuant to Rule 65 (b) Fed. R. Civ. P., a party moving for a Temporary Restraining Order must demonstrate that [sic] a likelihood of success on the merits of the case; that he will suffer immediate, irreparable injury as a result of the conduct of the adverse party; that his claims are not redressible in an action of law; and that the Temporary restraining Order would not contravene the interest of the public.

IND AND GMP APPLICATIONS

With regard to the IND application, Exhibit Fifty-eight, which is a letter dated April 1985, was a request from the FDA for additional information. That was the last communication regarding the processing of the IND. The Court did

---

[1] The same grounds applied equally to Defendants' Motion to Show Cause why the Government should not be held in Contempt and Motion for Equitable Return of Property.

not hear any testimony that Dr. Burzynski complied with that request. The Court viewed the letters going back and forth and listened to Dr. Burzynski talk about problems that he perceived he had encountered in trying to respond to the FDA. There were discrepancies concerning the request for the tablets and those were corrected by the FDA to read capsules, but still the FDA also requested solution studies in order to complete its review for the IND. Further, there is a provision, recalling Dr. Hazelwood's testimony for waiver of requested information. That provision would permit Dr. Burzynski to write the FDA and tell them that its request for male or female mice solution studies would not be necessary because the circumstances surrounding A 10 research nullify the effect of solution studies. The evidence does not show that Dr. Burzynski acted on that provision.

Further, and most importantly, there is no evidence in the Court's view, that Dr. Burzynski had been treated differently than any other applicant for an IND. The Court recognizes that it would be impossible for Dr. Burzynski to present, by way of example, someone who has applied for an IND application for the use of antineoplastons, because Dr. Burzynski is the only person who is applying for an IND for the use of antineoplastons. Yet, the Court is not holding him to that standard. There is no testimony that anyone was treated differently even in applying for an IND for the use of any cancer treatment which would be more analogous or even for a non-cancer drug treatment. There is just no evidence of any disparate treatment by the FDA.

Based upon the above, the Court finds that Defendants (cross-plaintiffs) have failed to establish a likelihood of

success on the merits with regard to the IND.

With regard to the GMP, on February of 1985, the last response from Dr. Burzynski was sent to the FDA. At that time, the FDA was in a position to respond to the GMP request and it hasn't done so, but the government has stated in open Court that it will give a response. The FDA is not committing itself to what the response will be, but will give a response within five (5) days of the date of this order.

FALSE AND MISLEADING INFORMATION

The second issue under consideration was the claim that the FDA disseminated false and misleading information. There are several exhibits (exhibits thirteen, fourteen, fifteen particularly, fifty-five, and fifty-six) which Defendants pointed out to the Court. The Court recalls the testimony very well. The Courts [sic] finds that it was misleading for the FDA to include a statement, as the one in Exhibit Fifteen, that in spite of the injunction Dr. Burzynski caused interstate distribution of antineoplastons. This Court has not made a determination that Defendants have engaged in interstate distribution of A 10, and there is no criminal indictment, even though the government is in the process of securing one, charging that Defendants have in fact engaged in that unlawful activity.

Moreover, the Court finds that it is not necessary for the FDA to provide patients and third parties with information regarding the search warrant. However, based on the testimony adduced at the hearing, the Court would not go so far as to find that Mr. Ewing was acting in bad faith when he

disseminated that information. The Court certainly would find that it exceeds his duties and responsibilities as an officer of the FDA. In the Court's judgment it is inappropriate for the FDA to release that information to patients and third parties. That information has nothing to do with the inquiries received by the FDA—whether the FDA has approved the IND application for the A 10 antineoplaston.

Defendants have shown by testimony that the above conduct has had an impact on their ability to treat patients because over fifty percent of their income is derived from insurance payments. The Court has heard testimony that some of the claims have been denied as a result of the FDA's response letters. The problem did not arise until the search warrant was issued and various third parties began requesting information from the FDA about A 10 antineoplastons. There is no evidence which indicates that the FDA maliciously released the above information for the purpose of destroying the reputation of Dr. Burzynski or his institute.

In any case, the Court would admonish the FDA about giving information regarding the conclusion that antineoplastons were caused to be shipped interstate and regarding any reference to the search warrant. The Court would encourage the parties to get together and come up with a suggestion as to what kind of information should be given to the patients and third parties regarding Dr. Burzynski's research and IND application for A 10 antineoplaston. The Court understands the position of Dr. Burzynski and his belief in the drug A 10, but the FDA has an obligation that is broader than mere regulation of new drugs: its obligation is to protect, as it envisions, the public at large and to give the

public essential information regarding the status of a new drug.

With respect to the Defendants' claim that the FDA maliciously withheld favorable information from the Defendants' IND, the testimony establishes that the FDA cannot give out the IND information to the public except under certain defined exceptions, which were not met. 21 C.F.R. §§312.5, 314.14 (1985).

Another issue is the FDA's non-approval of foreign shipments. That is an issue that was raised in Dr. Burzynski's affidavit filed on behalf of Defendants' motions. After listening to the testimony, the Court finds that Defendants have failed to establish that the government is in contempt of the Court's order of May 24, 1984, or that there is a likelihood of success on the merits that the FDA improperly disallowed foreign shipments. Dr. Burzynski testified that he actually had no evidence whether the clinics in the foreign countries, to whom the shipments were made, were using the A 10 antineoplaston for clinical studies as required by the FDA. Dr. Burzynski's position is simple: He stated that he was not the "KGB" and it was not his job to police the use of A 10 antineoplaston once it was shipped to foreign clinics.[1]

The government's evidence demonstrates that there was some misuse of A 10 antineoplaston in Canada.

---

[1] Dr. Burzynski also took the same position with respect to the FDA's allegations that his patients were transporting A 10 antineoplaston outside the State of Texas.

VALIDITY OF THE SEARCH WARRANT

Finally, the Defendants and Intervenors claim that the FDA wrongfully seized the patient records of Dr. Burzynski. Defendants and Intervenors claim that the search warrant should be declared invalid, because the FDA was engaged in harassing tactics when it applied for and received the search and seizure warrant.

The Defendants' and Intervenors' attack on the FDA's seizure of the patient records amounts to an attack on the validity of the search warrant authorizing that action. The United States Supreme Court devised a standard for determining whether to allow an evidentiary hearing on the veracity of an affidavit to a search warrant. In *Franks v. Delaware*, 438 U.S. 154 (1978), the Court held that:

> There is, of course, a presumption of validity with respect to the affidavit supporting the search warrant. To mandate an evidentiary hearing, the challenger's attack must be more than conclusory and must be supported by more than a mere desire to cross-examine. There must be allegations of deliberate falsehood or of reckless disregard for the truth, and those allegations must be accompanied by an offer of proof. They should point out specifically the portion of the warrant affidavit that is claimed to be false; and they should be accompanied by a statement of supporting reasons. Affidavits or sworn or other reliable statements of witnesses should be furnished, or their absence satisfactorily explained. Allegations of negligence or innocent mistakes are insufficient. The deliberate falsity or reckless disregard whose impeachment is

> permitted today is only that of the affiant, not of any nongovernmental informant. Finally, if these requirements are met, and if, when material that is the subject of the alleged falsity or reckless disregard is set to one side, there remains sufficient content in the warrant affidavit to support a finding of probable cause, no hearing is required. On the other hand, if the remaining content is insufficient, the defendant is entitled, under the Fourth and Fourteenth Amendments, to his hearing. Whether he will prevail at that hearing is, of course, another issue. *Id.* 171-172.

Applying *Franks v. Delaware* to this case, the Court finds that Defendants and Intervenors have failed to make a sufficient showing to entitle them to a hearing challenging the validity of the search warrant. The Court is not making a determination as to whether or not the search warrant was supported by probable cause. The conclusion reached is only that Defendants and Intervenors have failed to make an evidentiary showing that would entitle them to a hearing.

With respect to Dr. Burzynski's need for the records to treat his patients, the FDA has agreed, and consistently offered, to allow Dr. Burzynski access to the records, including the opportunity to copy them. There is no evidence that supports the proposition that an opportunity would not be made available to him to secure a copy of those documents in sufficient time to treat his patients effectively.

Intervenors make a separate plea for return of the patient records on the basis that the bits of information in the records are protected communications under a physician-patient privilege as enunciated under the state law in Tex.

Rev. Civ. Stat. Art. 4495B. Intervenors also claim that the patients have a constitutional right to privacy, which mandates return of their records. With the exception of specific federal statutes which do not apply here, there is not patient-physician privilege in federal criminal law. *United States v. Meagher*, 531 F.2d 752 (5th Cir. 1976) *cert. denied*, 429 U.S. 853 (1976). Moreover, this Court concludes that Article 4495B is not applicable to this case, because the seizure of the patient records was initiated by a valid search warrant pursuant to an ongoing federal criminal investigation. Even Article 4495B makes exceptions to the privilege against disclosure of patient records where there is a criminal prosecution and the patients are victims, or witnesses. The Intervenors have not cited any cases where Article 4495B has been applied to a federal criminal investigation. As a result, the Court concludes that Article 4495B does not warrant return of the patient records.

With regard to Intervenors' claim of privacy, the Court concludes that the Intervenors' interest, if any, does not entitle them to return of property. Assuming that Intervenors have a possessory interest in the records, that interest is not substantial enough to establish a right under the Fourth Amendment to the United States Constitution. The ultimate test is whether Intervenors have an expectation of privacy in the area searched. *Dickens v. Lewis*, 750 F.2d 1251 (5th Cir. 1984); *United States v. Salvacci*, 448 U.S. 83 (1980). There is no question that the Intervenors do not have a possessory interest in the business premises of Dr. Burzynski other than an interest in uninterrupted treatment. The evidence demonstrated Dr. Burzynski's ability to view

and copy records. The expectation of privacy, if any, is constrained to the information within the records, but does not extend to the business premises of Dr. Burzynski. As a result, the patients did not have an expectation of privacy in the business premises of Dr. Burzynski, which were searched pursuant to a search warrant.

In addition, with regard to the right of privacy, there must be a balancing between the privacy interests of the patients and the Government's duty to initiate and pursue criminal investigations. The government has initiated criminal proceedings. The evidence discloses that Intervenors have completed copies or are in the process of receiving completed copies of all of their patient records. Moreover, the evidence shows that the Government is taking extreme care to prevent patient information from being disclosed to unauthorized individuals. That evidence, along with the Government's need for the records to conduct their [sic] criminal investigation, is sufficient to protect the privacy interest of the patients. Intervenors have failed in their burden to establish that they have a superceding right to return of the patient records. For the foregoing reasons, Intervenors are unable to demonstrate a likehood [sic] of success on their Motion for Preliminary Injunction and Motion for Return of Property.

Accordingly,

It is ORDERED that Defendants' Motion for a Preliminary Injunction, Motion to Show Cause Why the Government Should Not be Held in Contempt, and Motion for Equitable Return of Property are hereby DENIED.

It is further ORDERED that Intervenors' Motion for a Preliminary Injunction and Motion for Return of Property are hereby DENIED.

The Clerk shall file this Order and provide a true copy to counsel for all parties.

DONE at Houston, Texas, this 21st day of January, 1986.

/s/ GABRIELLE K. McDONALD
UNITED STATES DISTRICT JUDGE

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA,	§	
Plaintiff,	§	
V.	§	C.A. NO. H-83-2069
BURZYNSKI CANCER RESEARCH INSTITUTE, ET AL.,	§	
Defendants.	§	

ORDER

Pending before the Court is Plaintiffs' (Counter-Defendants) Motion to Dismiss Counterclaims or for Summary Judgment. Upon consideration of the Motion and the Court's Order denying Defendants' and Intervenors' Motions for a Temporary Restraining Order and Motions for Return of Property, the Court concludes that the Plaintiffs' Motion to Dismiss for failure to state a claim should be Granted.

On October 23, 1985, the Court concluded a three week hearing on Defendants' and Intervenors' Motions for a Temporary Restraining Order and Motion for return of property. The claims raised in those Motions were primarily based upon the FDA's seizure of patient records from Dr. Burzynski's business premises. The defendants' counter-

claim for damages and injunctive relief is based upon the identical issues raised in Defendants' and Intervenors' Motions for Temporary Restraining Order and Motion for Return of Property. The Court does not have to repeat its consideration of those issues, because the issues raise legal questions which were decided against the Defendants and Intervenors in the hearing of October 23, 1985. For all of the above reasons the Court concludes that the Plaintiffs' Motion to Dismiss for Failure to State a Claim must be Granted. Accordingly,

It is ORDERED, ADJUDGED, and DECREED that the Plaintiffs' Motion to Dismiss Defendants' counterclaims and Intervenors' counterclaims is hereby GRANTED.

The Clerk shall file this Order and provide a true copy to counsel for all parties.

Done at Houston, Texas, this 21st day of January, 1986.

/s/ GABRIELLE K. McDONALD
UNITED STATES DISTRICT JUDGE

APPENDIX D

SEARCH WARRANT ON WRITTEN AFFIDAVIT

United States District Court
Southern District of Texas
UNITED STATES OF AMERICA
v.
An office complex at 6221 Corporate Drive, Houston, Texas

MAGISTRATE'S CASE NO.
H-85-321M

TO:
Any United States Marshall and Compliance Officers and Investigators of the United States Food and Drug Administration

Affidavit(s) having been made before me by the below-named affiant that he/she has reason to believe that (on the premises known as) an office complex at 6221 Corporate Drive, Houston, Texas, and further identified in the attached description in the Southern District of Texas there is now being concealed certain property, namely

Records and other property, including antineoplastons, of Stanislaw R. Burzynski, M.D., Burzynski Research Institute, Incorporated, Cameron Frye, and North American Consultants, Limited, that reflect:

(a) distribution of antineoplastons outside the State of Texas;
(b) the true addresses of persons to whom antineoplastons have been and are being distributed;
(c) patient treatment, patient accounts, and patient billings; and
(d) insurance claims and receipt of insurance payments

that show that antineoplastons have been and are being distributed in interstate commerce in violation of Title 21, United States Code 331(d) and the injunction of this Court and that evidence violations of Title 18, United States Code, Sections 286, 287, 371, 401, 1001, 1341, and 1505.

and as I am satisfied that there is probable cause to believe that the property so described is being concealed on the person or premises above-described and the grounds for application for issuance of the search warrant exist as stated in the supporting affidavit(s),

YOU ARE HEREBY COMMANDED to search on or before 10 DAYS (not to exceed 10 days) the person or place named above for the property specified, serving this warrant and making the search (in the daytime - 6:00 A.M. to 10:00 P.M.) and if the property be found there to seize it, leaving a copy of this warrant and receipt for the property taken, and prepare a written inventory of the property seized and promptly return this warrant to U.S. MAGISTRATE as required by law.

Kenneth P. Ewing
NAME OF AFFIANT

/s/ H. Lingo Platter
U.S. MAGISTRATE

12:27 P.M., July 16, 1985
DATE/TIME ISSUED

Description of Premises to be Searched

An office complex at 6221 Corporate Drive, Houston, Texas. The office complex houses the administrative offices of Stanislaw R. Burzynski, M.D., and Burzynski Research Institute, Incorporated, and until late April 1985, housed the office of Cameron Frye and North American Consultants, Limited.

AFFIDAVIT FOR SEARCH WARRANT

United States District Court
Southern District of Texas
UNITED STATES OF AMERICA
v.
An office complex at 6221 Corporate Drive, Houston, Texas

MAGISTRATES CASE NO.H-85-321M

NAME AND ADDRESS OF JUDGE[1]
OR FEDERAL MAGISTRATE:
5515 Rusk Avenue
Houston, Texas

The undersigned being duly sworn deposes and says: That he/she has reason to believe that on the premises known as

An office complex at 6221 Corporate Drive, Houston, Texas, and further identified in the attached description.

The following property is concealed:

Records and other property, including antineoplastons, of Stanislaw R. Burzynski, M.D., Burzynski Research Institute, Incorporated, Cameron Frye, and North American Consultants, Limited, and further identified in the attached description.

Affiant alleges the following grounds for search and seizure[2]
See attached affidavit.

Affiant states the following facts establishing the foregoing grounds for issuance of a search warrant
See attached affidavit.

/s/ Kenneth P. Ewing
Compliance Officer
U.S. Food and Drug Administration

Sworn to before me and subscribed in my presence

/s/ H. Lingo Platter
FEDERAL MAGISTRATE

July 16, 1985

---

[1] United States Judge or Judge of a State Court of Record.

[2] If a search is to be authorized "at any time of the day or night" pursuant to Federal Rules of Criminal Procedure 41(c), show reasonable cause therefor.

Description of Premises to be Searched

An office complex at 6221 Corporate Drive, Houston, Texas. The office complex houses the administrative offices of Stanislaw R. Burzynski, M.D., and Burzynski Research Institute, Incorporated, and until late April 1985, housed the office of Cameron Frye and North American Consultants, Limited.

Description of Property to be Seized

Records and other property, including antineoplastons, of Stanislaw R. Burzynski, M.D., Burzynski Research Institute, Incorporated, Cameron Frye, and North American Consultants, Limited, that reflect:

(a) distribution of antineoplastons outside the State of Texas;
(b) the true addresses of persons to whom antineoplastons have been and are being distributed;
(c) patient treatment, patient accounts, and patient billings; and
(d) insurance claims and receipt of insurance payments

that show that antineoplastons have been and are being distributed in interstate commerce in violation of Title 21, United States Code, Section 331(d) and the injunction of this Court and that evidence violations of Title 18, United States Code, Sections 286, 287, 371, 401, 1001, 1341, and 1505.

RETURN

DATE WARRANT RECEIVED 7-16-85

DATE AND TIME
WARRANT EXECUTED 7-17-85 9:30 a.m.

COPY OF WARRANT AND RECEIPT
FOR ITEMS LEFT WITH S.R. Burzynski, M.D.

INVENTORY MADE IN
THE PRESENCE OF Robert V. Holland, Jr.

INVENTORY OF PROPERTY TAKEN PURSUANT TO THE WARRANT

1 4-drawer file cabinet with billing records.
6 4-drawer file cabinets with patient records.
4 4-drawer file cabinets with insurance claims.
7 "dead accounts" insurance files.
Active and inactive patient billing cards.
Folder of miscellaneous notes of Cameron Frye.
Expandable file from B. Burzynski, M.D. office
containing shipping record
12 computer print-outs of patient names.
4 computer print-outs of patient billing records.
1 file "Canadian Patients Response."
1 file "Shipments to Germany."
2 files "Shipments to Poland."
1 file "Shipments to Columbia."
1 file "Shipments to Denmark."
1 file "Shipments to Brazil."
1 file drawer North American Consultants
correspondence.
1 set patient index cards from S. Burzynski's office.
From S. Burzynski, M.D. desk:
TWX concerning E. Ploch
List of Patients participating in TV programs.
Letter from Evelyn Oldaker.

List of patients owed money.
Memo of phone call with Olive Axford.
List of patients to check out.
Folder with handwritten notation of "shipments to patients."

2 insurance claim files from S. Burzynski's office.

1 envelope containing shipping documents collected from Receptionist's area and billing area.

5 file cabinet keys

Executed 7-18-85 14:09 before Helen L. Toombs

9 patient records

CERTIFICATION

I swear that this inventory is a true and detailed account of all the property taken by me on the warrant.

Subscribed , sworn to, and returned before me this date.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA,

v.

An office complex at 6221 Corporate Drive, Houston, Texas. The office complex houses the administrative offices of Stanislaw R. Burzynski, M.D., and Burzynski Research Institute, Incorporated, and until late April 1985, housed the office of Cameron Frye and North American Consultants, Limited.

AFFIDAVIT OF
KENNETH P. EWING

1. I am Kenneth P. Ewing, a Compliance Officer with the United States Food and Drug Administration (FDA) assigned to the Houston Station Office, Region VI. I have responsibility for reviewing investigative records of FDA and other evidence gathered by FDA to determine whether there are apparent violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. , and other statutes enforced by FDA. I have been a Compliance Officer with FDA since March 1974.

2. I have reviewed information and evidence gathered in the course of FDA inspections and investigations of Stanislaw R. Burzynski, M.D., and Burzynski Research Institute, Incorporated, and Cameron Frye and North American Consultants, Limited. Unless otherwise indicated,

the statements made below are based upon that information and evidence.

3. The administrative offices of Dr. Burzynski and Burzynski Research Institute, Incorporated, are housed in an office complex at 6221 Corporate Drive, Houston, Texas. Until late April 1985, the said office complex also housed the office of Cameron Frye and North American Consultants, Limited. North American Consultants, Limited, was operated solely by Cameron Frye and Mr. Frye's activities, discussed below both individually and through North American Consultants, Limited, were undertaken on behalf of and in conjunction with Dr. Burzynski and Burzynski Research Institute, Incorporated. I have no reason to believe that any records of those activities have been removed from the said office complex since late April 1985 when the association between Dr. Burzynski and the Burzynski Research Institute, Incorporated, and Cameron Frye and North American Consultants, Limited, was terminated.

4. Antineoplastons are new drugs within the meaning of 21 U.S.C. § 321 (p) which, pursuant to 21 U.S.C. § 355 (a), may not be introduced or delivered for introduction into interstate commerce since there is no approval by FDA of an application filed pursuant to 21 U.S.C. § 355 (b) for antineoplastons and clinical hold letters from FDA forbidding human experiments with antineoplastons were issued to Dr. Burzynski on May 31, 1983, December 15, 1983, and February 13, 1984, for a notice of claimed investigational exemption under 21 U.S.C.

§ 355 (i) and 21 C.F.R. § 312.1 filed by Burzynski Research Institute. Interstate distributions of antineoplastons is additionally specifically precluded by an Order of Permanent Injunction issued by this Court against Dr. Burzynski, among others, in United States v. Burzynski Cancer Research Institute, Civil No. H-83-2069, on May 24, 1983, and by a consent judgement entered by this Court against Cameron Frye and North American Consultants, Limited, in the same action on May 10, 1983.

5. On or about December 10, 1984, I received a telephone call from V.A. Randazzo, Metropolitan Insurance Companies, Schenectady, New York, inquiring about antineoplaston and advising that Donald D. Lecky, Clinton, Ohio, and insured, had received treatment by Dr. Burzynski and that Metropolitan Insurance Companies had subsequently received a claim from Dr. Burzynski for services that were not rendered.

6. On January 24, 1985, and February 5, 1985, FDA Investigator Michael B. Falkow of the Akron, Ohio, office of FDA visited Mrs. Rebecca A. Lecky, 1977 Rheam Road, Clinton, Ohio. Mrs. Lecky is the surviving spouse of Donald D. Lecky and was present with him at all times when he was treated by Dr. Burzynski.

Mrs. Lecky and her husband visited Dr. Burzynski at 6221 Corporate Drive, Houston, Texas, on June 29, 1984, when they were given a quantity of antineoplaston, for which they paid $5330, to take back to Ohio with them. They remained in Houston until June 25 or 26, 1984.

On June 20, 1984, Cameron Frye, then a Burzynski associate, told the Leckys that they should return to Houston for additional treatment and medication. They declined and were then told by Frye to establish a Texas address to which the medication could be shipped. They stated that could not be done either. It was at this point that the drug was given to them. Mr. Frye advised them to postdate a check for the drug in order to obtain "enough treatment." A check numbered 1844 dated June 20, 1984, in the amount of $1500 and a second check numbered 1845 dated June 27, 1984, in the amount of $3830 were issued by Donald Dale Lecky. The former check is stamped on the reverse with the date "Jun 21 84." The latter check is stamped in the reverse with the date "Jun 25 84."

The drug given to the Leckys was in a bottle labeled in part:

> Antineoplaston A10 500 mg Capsules
> Lot No. 222CEx 1284 *** Burzynski Research Institute, Stafford, Texas ***
>
> Caution
>
> 1. To be distributed and used for investigational use solely within the State of Texas.
>
> 2. To be administered and dispensed only by Dr. S.R.

Burzynski, 6221 Corporate Drive, Houston, Texas.

Caution: New Drug - Limited by Federal Law to investigational use for which it is not approved ***

The Leckys received a receipt dated June 25, 1984, for $5330, which specifies 21 days of treatment from June 27 to July 17, 1984. Mrs. Lecky informed Investigator Falkow that Mr. Lecky was neither in Houston nor treated by Dr. Burzynski during the period June 27 to July 17, 1984, or at any time thereafter.

On or about November 24, 1984, Mrs. Lecky received at her home in Ohio and unsolicited shipment of 8 bottles of 20/500 mg. capsules of antineoplaston from Cameron Frye, 12227 Burgoyne, Houston, Texas, via Purolator Courier Corporation (PCC). That shipment is covered by PCC Bill of Lading (B/L) 13274943 dated November 21, 1984. Investigator Falkow collected the entire package from Mrs. Lecky. The package was a standard Purolator Courier Puropak with the said bill of lading attached to the outside. The package contained eight bottles labeled in part:

Antineoplaston A3, 500 mg Capsules
20 Capsules *** Burzynski Research Institute, Stafford, Texas ***

Caution

1. To be distributed and used for investigational use solely within the State of Texas.

2. To be administered and dispensed only by Dr. S.R. Burzynski, 6221 Corporate Drive, Houston, Texas. ***

Caution: New Drug - Limited by Federal Law to investigational use for which it is not approved. ***

On or about August 6, 1984, Mrs. Lecky received an Explanation of Benefits from General Electric Insurance Plan (administered by Metropolitan Insurance Companies) which reflects payment of $2457.35 to Dr. Burzynski for treatment from June 20 to July 3, 1984.

On or about August 24, 1984, Mrs. Lecky received an Explanation of Benefits from General Electric Insurance Plan which reflects payment of $2142 to Dr. Burzynski for treatment from July 4 to July 17, 1984.

On or about September 7, 1984, Mrs. Lecky received an Explanation of Benefits from General Electric Insurance Plan which reflects payment of $4218.23 to Dr. Burzynski for treatment from July 18 to July 31, 1984.

Of the total paid by the Leckys and General Electric Insurance Plan, $14,147.58, for a bill of $5330, Mrs. Lecky has received a refund of only $1000. That refund was received by Mrs. Lecky on or about November 20, 1984.

7. By letter dated February 22, 1985, I requested copies of the Lecky file from Vincent Randazzo. Mr. Randazzo's response of March 7, 1985, with enclosures, reflects total payment to Dr. Burzynski of $14,147.58.

8. Attached to Mr. Randazzo's letter are the following:

(a) An insurance claim form dated July 26, 1984, for Donald D. Lecky and signed "S.R. Burzynski."

(b) A letter on S.R. Burzynski letterhead dated July 26, 1984, and signed "Cameron Frye," stating, among other things, that Mr. Lecky authorized payment of all medical benefits directly to Dr. Burzynski.

(c) An insurance claim form dated August 14, 1984, for Donald D. Lecky and signed "S.R. Burzynski."

(d) A letter on S.R. Burzynski letterhead dated August 14, 1984, and signed

"Cameron Frye," stating among other things, that Mr. Lecky authorized payment of all medical benefits directly to Dr. Burzynski.

(e) An insurance claim form dated August 21, 1984, for treatment of Donald D. Lecky from July 18 to July 24, 1984, and signed "S.R. Burzynski."

(f) An insurance claim form dated August 21, 1984, for treatment of Donald C. Lecky from July 24 to July 31, 1984, and signed "S.R. Burzynski."

(g) A letter on S.R. Burzynski letterhead dated August 21, 1984, and signed "Cameron Frye," stating, among other things, that Mr. Lecky authorized payment of all medical benefits directly to Dr. Burzynski.

9. On or about January 30, 1985, in response to a previous inquiry, I spoke by telephone with Ann Skelley, Insurance Department, Borden, Incorporated, 2040 Brice Road, Reynoldsburg, Ohio.

Ms. Skelley informed me that Greg Talbot, the son of their insured, Camille Talbot, 3012 Gallo Drive,

Chalmette, Louisiana, had received treatment from Dr. Burzynski.

Borden, Incorporated, received statements and insurance claim forms from S.R. Burzynski for treatment of Greg Talbot on the following dates:

(a) September 29 through October 15, 1984, for seven treatments per day at $45.00 per treatment.

(b) October 19 through October 25, 1984, for seven treatments per day at $45.00 per treatment.

(c) October 26 through November 1, 1984, for seven treatments per day at $45.00 per treatment.

(d) November 2 through November 8, 1984, for seven treatments per day at $45.00 per treatment.

(e) Claims identified as (a) and (d) above had letters attached on S.R. Burzynski letterhead, both signed "Cameron Fryē" and dated respectively October 2, 1984, and November 3, 1984, which stated that the patient authorized all medical

benefits be paid directly to Dr. Burzynski.

Mrs. Talbot submitted PCC invoices to Borden, Incorporated, for payment as follows:

(f) B/L 053510133 dated September 19, 1984, for $21.00 with a handwritten notation "cancer medicine sent from Houston - Dr. Burzynski."

(g) B/L 053510146 dated September 25, 1984, for $11.75.

(h) B/L 053510468 dated October 8, 1984, for $57.00.

10. I have been informed by confidential informants whose information has been corroborated that double-billing and over-billing of insurance carriers is standard procedure at Burzynski Research Institute, Incorporated:

(a) One of the schemes used was to charge $180 per day for antineoplaston. The patient would be charged 25% of that sum and the insurance carrier would be simultaneously charged 100%.

(b) Cameron Frye would assure that new patients signed 10 to 20 blank insurance claim forms on their first visits. Although patients made substantial payments, usually in excess of $5000, for their treatment, charges were also submitted directly from the Institute to the insurance carriers. Even when patients became aware of such double-billing and over-billing and requested refunds, complete refunds were seldom, if ever, made.

(c) In preparing insurance claim forms, both for private carriers and medicare, Frye used an acronym ("ANPA") or the term "cancer chemotherapy" to disguise the fact that the treatment was actually with unapproved antineoplastons. For medicare claims, Frye used the code "9412." An inquiry to Blue Cross, the administrator of medicare in Texas, revealed that "9412" is a code for "IV administration for chemotherapy for malignant disease."

11. Investigator Sharyn Miller of the Houston FDA office conducted an investigation at PCC from December 19, 1984, to February 25, 1985. Her

investigation disclosed that PCC has assigned the following account numbers to S.R. Burzynski, Cameron Frye, and their related business entities:

9079483	S.R. Burzynski, M.D.
1470334	Burzynski Research Institute
5560288	Cameron Frye
5281687	Cameron Frye
2935137	North American Consultants, Limited

Dr. Burzynski's business address is on a route designated 2102 by PCC where routine pickup of shipments is made by a PCC employee. The PCC bill of lading includes the account number, B/L number, and route number as well as the shipper name and destination. There were 212 records found of shipments made from route 2102, bearing one of the account numbers listed above, during 1984. Twenty-eight of the shipments were to Texas addresses, the remainder were to various destinations outside Texas.

12. The information obtained at PCC was updated on May 14, 1985. Records of at least 36 shipments made between March 1 and April 24, 1985, and thought to be antineoplaston were obtained. Each of the records bear route number 2102, one of the account numbers listed in paragraph 11 above, and an address of a consignee outside the State of Texas.

13. A number of confidential informants whose information has been corroborated have stated to me that records at Burzynski Research Institute, Incorporated, to which FDA has access have been systematically altered to conceal the true home addresses of patients who reside outside Texas. Patients are told to establish a "Texas address" which is marked on various patient records that may be reviewed by FDA. True home addresses are recorded only on patient billing records and insurance records that are concealed from FDA. The only drugs of which FDA or its informants are aware that are shipped from Burzynski Research Institute, Incorporated, are antineoplastons. On shipments within the State of Texas the PCC bills of lading completed at the Institute routinely state that the contents are "medicine." However, for shipments outside of Texas, the bills of lading state that the contents are "personal items" or "literature."

14. Based on Investigator Miller's investigation at PCC, I have reason to believe that there may be on the premises at 6221 Corporate Drive, Houston, Texas, one or more shipments of antineoplastons, addresses to one or more persons outside the State of Texas awaiting pick-up by PCC.

15. Based on the foregoing, and on FDA inspections and information from confidential informants whose information has been corroborated, I believe that one or more of the rooms at the said office complex at 6221 Corporate Drive, Houston, Texas, are used for, among other

things, storing, maintaining, and concealing various records and other property, including antineoplastons, that reflect:

(a) distribution of antineoplastons outside the State of Texas;
(b) the true addresses of persons to whom antineoplastons have been and are being distributed;
(c) patient treatment, patient accounts, and patient billings; and
(d) insurance claims and receipt of insurance payments

that will show that antineoplastons have been and are being distributed in interstate commerce in violation of 21 U.S.C. § 331(d) and the injunction of this Court and that will evidence, among other criminal violations, violations of 18 U.S.C §§ 286, 287, 371, 401, 1001, 1341, and 1505.

/s/ KENNETH P. EWING
Compliance Officer
U.S. Food and Drug Administration

Sworn to before me and subscribed in my presence, this 16th day of July, 1985.

/s/ H. Lingo Platter
United States Magistrate
Houston, Texas

APPENDIX E

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 86-2183

UNITED STATES OF AMERICA,

Plaintiff-Counter Defendant-Appellee,

versus

BURZYNSKI CANCER RESEARCH INSTITUTE, ET AL.,

Defendants-Counter Plaintiffs-Appellants,

versus

JUANICE KUHARZYK, ETC., ET AL.,

Intervenors-Counter Plaintiffs-Appellants.

Appeal from the United States District Court for the Southern District of Texas

---

ON PETITION FOR REHEARING

(August 26, 1987)

Before: RUBIN, RANDALL and JOHNSON, Circuit Judges.

Per Curiam:

IT IS ORDERED that the petition for rehearing filed on behalf of Kuharzyk, et al., in the above entitled and numbered cause be and the same is hereby denied.

ENTERED FOR THE COURT:

/s/ Alvin B. Rubin
United States Circuit Judge